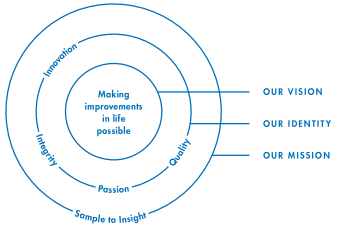
Exhibit 94

INSIGHTS

THE QIAGEN MAGAZINE 2020

Sample to Insight

QIAGEN



OUR VISION

At the core of a great company is the ambition to make a difference. It answers the question why a company exists. At QIAGEN, we have a truly exciting vision, and the future we seek is meaningful – making improvements in life possible.

OUR MISSION

Our mission defines our purpose, what we do and how we make an impact. As the innovative market and technology leader, QIAGEN creates Sample to Insight technologies that enable access to valuable molecular insights from any biological sample. Our mission is to make improvements in life possible by enabling our customers to achieve outstanding success and breakthroughs in life sciences, applied testing, pharma and molecular diagnostics.

Our commitment to the markets, customers and patients we serve drives our innovation and leadership in all areas where our Sample to Insight technologies are required. The exceptional talent, skill and passion of our employees are key to QIAGEN's excellence, success and value.

OUR CULTURE

Our 3i framework expresses our culture, leadership principles and how we act at QIAGEN. It anchors our aspirations of focus, accountability and entrepreneurial decision-making.

Identity
Our culture is shaped by our values
Passion / Quality
Integrity / Engagement
Innovation

Inspire
Our leadership style transmits our values and inspires our employees
Influence / Motivate
Stimulate / Develop

Impact
Our value-based actions make the difference
Entrepreneurial decision-making /
Focus / Accountability

OUR PEOPLE

The greatest strength of QIAGEN is our people.
Their diversity, energy, expertise
and creativity are critical to our success.

> 5,200
employees worldwide

> 70
nationalities

34
countries with direct QIAGEN operations

OUR STRATEGY

Our strategy is to address the rapidly changing needs of our customers, providing solutions that enable them to gain valuable molecular insights from any biological sample. As we implement our strategy, we focus our teams on five priorities to create value for our stakeholders.

Accelerate growth
We focus on key franchises, driving growth across the customers we serve worldwide.

Enhance growth with acquisitions and integration
We complement internal R&D with new business opportunities that strengthen our Sample to Insight portfolio.

Deliver efficiency and effectiveness
We are rethinking how we work, embracing agile teams, digitization trends and building better productivity.

Increase value of QIAGEN as employer of choice
We are building a culture of diversity in which our employees can fully apply their talent and energy and share in the rewards.

Enhance customer experience
We are determined to exceed the expectations of our customers in helping them gain the insights they seek.

Sample to Insight is our strategic framework that puts the needs and challenges of our customers front and center.

We want to identify key challenges holding customers back and to deliver solutions so they can achieve greater success, ultimately helping them exceed their own expectations and gain the insights critical for their work.

HOW CAN MOLECULAR TESTING HELP FIGHT A PANDEMIC?

In any viral outbreak, molecular testing is critical to rapidly identify and isolate new patients and those who have come into contact with them. QIAGEN has worked together with governments to provide infectious disease testing in global crisis situations including the SARS, avian and swine flu outbreaks, and, most recently, the novel coronavirus pandemic.

WHAT CAN MICE THAT HAVE TRAVELED TO THE "ROOF OF THE WORLD" TEACH US ABOUT SPORTS DOPING?

Gene doping is a form of athletic performance enhancement related to the stimulation of red blood cell production. Researchers aiming to develop new molecular testing methods for detection of gene doping took live mice with them on an expedition to the top of Mount Everest. Using QIAGEN testing kits they studied tissue and blood samples from the mice to uncovered molecular signatures of altitude-induced hypoxia.

WHAT CAN BACTERIA TELL US ABOUT ENVIRONMENTAL DISASTERS?

Bacteria are present in every environment on planet Earth – from the depths of the ocean to the highest mountain peaks. Bacterial populations undergo rapid changes in size and composition in response to environmental changes, making them a perfect biomarker. QIAGEN's microbiome kits have been used by researchers to study bacterial community fluctuations in response to oil spills, forest fires and climate change, providing insights into the environmental impact of these disasters on the world around us.

WHAT DO HIGH TECH DIAGNOSTICS AND WORLD CLASS SPORT HAVE IN COMMON?

Respiratory infections are the most common diseases to impact elite athletes. Surprising though it may seem, the intense training regimes necessary to achieve peak performance to compete at an international level put the immune system under strain, leading to higher susceptibility to infection. QIAGEN's QIAstat-Dx solution for syndromic testing is being used to gain rapid diagnosis of symptoms by international basketball teams and premier league football teams, and was even planned for use at the 2020 Olympic Games in Japan before they were postponed to 2021 due to the coronavirus pandemic.

WHAT HAPPENS TO THE HUMAN BODY IN ZERO GRAVITY?

When NASA put retired astronaut Scott Kelly into space for one year, they had no idea what physiological, molecular or cognitive differences they would observe compared to his twin brother, who remained back on Earth. Aided by QIAGEN solutions they made discoveries about telomere length – these end caps of the chromosomes grew by an average of 14.5% in orbit, and shrunk to their original length after returning to Earth – and DNA methylation that provided insights into the hazards of long-term space habitation.

Contents

The path forward: Decisions on the future of QIAGEN make an even bigger difference

THIERRY BERNARD, Chief Executive Officer, QIAGEN

Thierry Bernard and Roland Sackers discuss an eventful 2018, an unprecedented start to 2020, and QIAGEN's plans for building value with differentiated Sample to Insight solutions.

The start of 2020 was marked by news of QIAGEN's agreement to be acquired by Thermo Fisher Scientific and response to the public health emergency with the novel coronavirus. First, what are your perspectives on QIAGEN's proposed acquisition?

THIERRY BERNARD We are excited about the future. At the same time, we are focusing on how best to anticipate and manage developments in 2020. Our vision at QIAGEN has always been to make improvements in life possible with our differentiated Sample to Insight solutions for molecular testing. This strategic step with Thermo Fisher will enable us to enter a promising new era and give our employees the opportunity to have an even greater impact. As a mid-cap company, we are constantly looking for strategic critical mass, and Thermo Fisher's larger global scale and reach will help us expand our scope to ensure continued growth of the QIAGEN business.

ROLAND SACKERS We worked hard to achieve an attractive transaction, and both companies' boards unanimously approved this agreement. This combination is designed to deliver significant cash value to our shareholders, while enabling us to accelerate the expansion of our solutions so customers worldwide can achieve breakthroughs advancing the science of life and improving health outcomes. The transaction is expected to be completed in the first half of 2021.

The coronavirus pandemic caught the world by surprise. What is QIAGEN doing to help respond to the public health emergency?

TB The coronavirus emergency goes to the heart of our mission and our expertise. As soon as it became clear this outbreak was serious and spreading quickly, we started receiving calls from customers in need of testing solutions. In the first three months of 2020, we have already shipped twice as many sample preparation kits and instruments – cited by name in the U.S. Centers for Disease Control instructions for coronavirus testing – to some geographies as we did in all of 2019. We have responded to the unprecedented demand by dramatically increasing manufacturing capacity and moving to 24/7 operations at our sites in Germany, the U.S. and Spain. QIAGEN teams also sprang into action to add the new SARS-CoV-2 virus strain to our QIAstat-Dx respiratory panel, manufacture and validate it, and begin distributing kits to customers around the world. Our employees have risen to this challenge.

ROLAND SACKERS, Chief Financial Officer, QIAGEN

All of this has happened following the decision of Peer M. Schatz to step down as CEO after 27 years with the company in October 2019.

R S Yes, we have come together quickly in the Executive Committee as a new leadership team and have been guiding QIAGEN through this period of significant change. It's been a successful transition, and QIAGEN is on course in 2020.

T B Absolutely. On behalf of my colleagues in the Executive Committee, and all of our employees, I would also like to thank Peer for his exceptional contributions and impact on QIAGEN. He has played a key role in creating a true success story in the life sciences and diagnostics. QIAGEN is a company that has enabled great advances in science and healthcare. We wish Peer all the best in his future endeavors.

How do you view QIAGEN's prospects in 2020?

T B QIAGEN is in a strong underlying position with a unique portfolio and multiple engines of growth in the molecular testing market. Our 5,100 employees are known for deep expertise and commitment to helping customers, and these relationships continue to drive our business forward. Challenges this year include launching our innovative new QIAcuity solutions for digital PCR; bringing accurate modern testing for latent tuberculosis infection to large and needy parts of the world with QuantiFERON-TB Access; driving continued growth in placements of the QIAsymphony automation system; and delivering sales growth trends for QIAStat-Dx in line with our initial expectations. We also need to accelerate the full integration of our QIAGEN Digital Insights portfolio and transform our new partnership with Illumina that was announced in October 2019 into a success story in next-generation sequencing for clinical testing.

How has QIAGEN changed as a result of the events in 2019?

R S We have made important organizational changes that included integrating global sales resources into our three business areas and moving additional activities into shared business service centers. The result is a more focused, agile and efficient global operation to drive the growth of our solutions.

T B I fully agree. We have emerged with a strong focus on execution to create value through financial disciplines and organizational changes. The fundamentals of our business model are extremely solid. We are streamlining our portfolio to allocate resources only to markets where QIAGEN can be a leader – number 1, 2 or 3. Our change in NGS strategy frees up resources and offers a faster track to widespread adoption of our NGS solutions in clinical diagnostics.

The big product launch for 2020 is digital PCR. What does this platform offer for QIAGEN and how do you see your prospects?

T B We are on track for a mid-2020 launch of fully integrated digital PCR workflows, branded as QIAcuity and delivering key advantages over existing systems for digital PCR. QIAcuity systems with unique nanoplate technology will offer researchers a cost-effective, highly reliable way to gain faster, easier access to digital PCR technology. A more accurate method than quantitative PCR, the current go-to technology to amplify and analyze nucleic acids, digital PCR is one of the fastest-growing areas in the Life Sciences. Pre-launch interest in QIAcuity is running high. We believe QIAcuity also provides a path to accelerate conversion of the much larger market for quantitative PCR, estimated at more than $4.5 billion a year.

You mentioned the upcoming launch, QuantiFERON-TB Access. How will this address the need for TB testing in high-disease-burdened regions?

T B QuantiFERON-TB Access will build on our existing QuantiFERON portfolio. It is specifically designed to make the benefits of QuantiFERON-TB Gold Plus available in areas of the world with low resources and limited infrastructure, but a high incidence of TB. The testing unit is compact and portable and can be operated outside of the lab to bring TB testing to the communities most in need. This expands the market substantially, serves a vital public health need and supports our global mission to help with the eradication of TB.

As a last point, the issue of sustainability is becoming increasingly important for stakeholders. How is QIAGEN approaching this topic?

R S It begins with our long-time mission of making improvements in life possible. We engage deeply with customers, from scientists aiming for breakthroughs in understanding life's processes, to medical and other professionals improving the health and well-being of millions. QIAGEN's mission inspires us to join the fight against global threats, like the ancient epidemic of tuberculosis and the current outbreak of coronavirus. From the start, we have designed products to make molecular testing safer for workers and the environment, and today we manage all aspects of our business to ensure environmental soundness and sustainability. Our Supervisory Board and executive team work with a keen sense of fiduciary responsibility and stewardship. We believe these practices are simply good business.

THIERRY BERNARD
joined QIAGEN in February 2015 to lead QIAGEN's growing presence in Molecular Diagnostics, the application of Sample to Insight solutions for molecular testing in human healthcare. He was named Chief Executive Officer in March 2020, after having previously served in this role on an interim basis.

ROLAND SACKERS
joined QIAGEN in 1999 as Vice President of Finance and has been Chief Financial Officer since 2004. In 2006, Mr. Sackers became a member of the Managing Board.

Behind the scenes at the museum

Five million people pass through the doors of London's Natural History Museum annually – but few of them are aware of the work going on behind the scenes in the museum's labs. Out of sight of the exhibition halls, sequencing expert Claire Griffin is on a quest to reveal insights into just about everything.

Claire Griffin opens a drawer and takes out a pile of zipper-locked bags containing samples that have been sent to her from all over the world. Each sample is unique: an unknown moth found in a wine bottle in Asia; a strange insect discovered in a Caesar salad in North America and a mosquito from France. Just recently, someone sent her an antique Japanese mask adorned with animal hair. The week before, an auction house asked her to identify the ivory inlay of a table. Her mission: to work out the best method to reveal the sample's secret, to identify the species, and do so, no matter what condition the sample may arrive in, at her lab.

"Wherever the samples come from, I use my experience to think about the kind of sample it is, its strengths and weaknesses, and what sequencing method makes the most sense for it," she explains. Griffin is responsible for maintaining the lab's Sanger sequencing system, as well as implementing quality control in the museum's sequencing lab. She sifts through the pile of various samples. "I've been working here for more than two decades and every day is different," she adds, nostalgically, "I must have seen thousands of samples in that time, all weird and wonderful in their own way."

In the early morning, London's Natural History Museum is eerily quiet. The only sounds are echoes of the early morning staff reverberating off the intricate walls. An enormous whale skeleton hangs in the entrance hall and adds to the atmosphere, before the museum officially opens and visitors flood into its halls.

Griffin's laboratory is hidden away in the labyrinthine catacombs spread out underneath the museum. Tucked away behind the exhibit walls, she seeks the answers to questions that someone, somewhere in the world, is desperately waiting for:

"I have helped analyze all kinds of items from the museum's collection – termites, spiders, reptiles, seaweed, jellyfish, bird excrement, 200-year-old bird foot pads, as well as the menagerie of other items, some decades old, that come in from private collections and auction houses," Griffin muses. The stranger the sample, the more likely it is to end up on her desk.

The samples are often in a deplorable state. They've been exposed to high temperatures or industrial processes – or they are old, degraded, and have come into contact with a wide variety of people and places. There are dehydrated and decomposed samples, moist and dry ones, some floating in preservatives, and others that have been subjected to extreme heat. The specimens are often contaminated with DNA from bacteria, fungi, or even rodents. Despite their state, the challenge is to prepare those samples in a way that allows Griffin to identify the DNA of the sample and not any false traces of the people or microorganisms they may have interacted with. "We use QIAGEN's nucleic acid extraction kits quite frequently," she says. "The blood and tissue kit is the one I opt for most often for a wide range of sample types, because it gives us high-quality DNA, even with tricky samples."

With mystery samples submitted to the lab from all over the world, Griffin's work can sometimes uncover unexpected results. DNA sequencing recently revealed the genetic signature of a wasp in an unknown ant species she received from Singapore. Initially suspected to be one of the contaminants she frequently encounters, the wasp actually turned out to be a never before seen species of parasite that lays its eggs in the ants. Thanks to Griffin's work, a new species of parasitic wasp was identified. It is cases like this that have helped Griffin build the remarkable reputation she has today.

She is also known for her expertise in identifying birds. "From the smallest remnants, I can determine not only the species but the sex," she says. "Once I've done the molecular ID, I can sometimes use the genomic DNA generated for PCR using sexing primers to allow me to establish the sex of the birds."

When the museum doors open to the queue of visitors outside, those visitors can often be found taking selfies next to the monument dedicated to Charles Darwin or the giant blue whale skeleton. It may be a day like any other at the Natural History Museum in London, but for Griffin, something unique always awaits. A new sample is currently sitting on her desk. A customer found a gecko in a bag of steamed vegetables from a UK supermarket. No one knows what species this is yet. But Griffin intends to find out.

The Natural History Museum offers scientists and researchers from around the world varied expertise in sequencing. It has its own in-house sequencing facility with services from extraction to sequencing. Claire Griffin and her team support students and their wide-ranging research endeavors, including troubleshooting to provide help when students have difficulties in certain areas with PCR, or with the types of sample tissues they may be working on.

In 2019, more than 300 museum scientists at the Natural History Museum described 412 new species and published more than 700 scientific papers with international collaborators. The exhibitions include 80 million animal specimens; 5,000 meteorites; and 500,000 rocks, gems and minerals, which span 4.5 billion years in time. The museum's library houses 1.5 million books, artworks and manuscripts.

The 1.5 microtubes ➔ 1, 6, 9, 11, 14 contain examples of the different materials Claire Griffin is working on, i.e., animal hair, insect legs and textile fragments. The bag of feathers ➔ 5 represents the work she does on bird identification. The falcon tube ➔ 8 shows examples of crop pests she helped identify. The blue whale skeleton ➔ 2 is on display in the museum's Hintze Hall. The museum has extensive collections of specimens ➔ 3, 4, 7, 10, 12, 13, 15 stored in its archives.

From Nobel Prize winners…

QIAGEN has been proud to support world-leading science from our earliest days through to the present. We are honored to include among our customers Nobel Prize-winning researchers whose groundbreaking discoveries have uncovered the secrets of the molecular world and steered the direction of future innovations, as well as many of our product developments.

CHRISTIANE NÜSSLEIN-VOLHARD

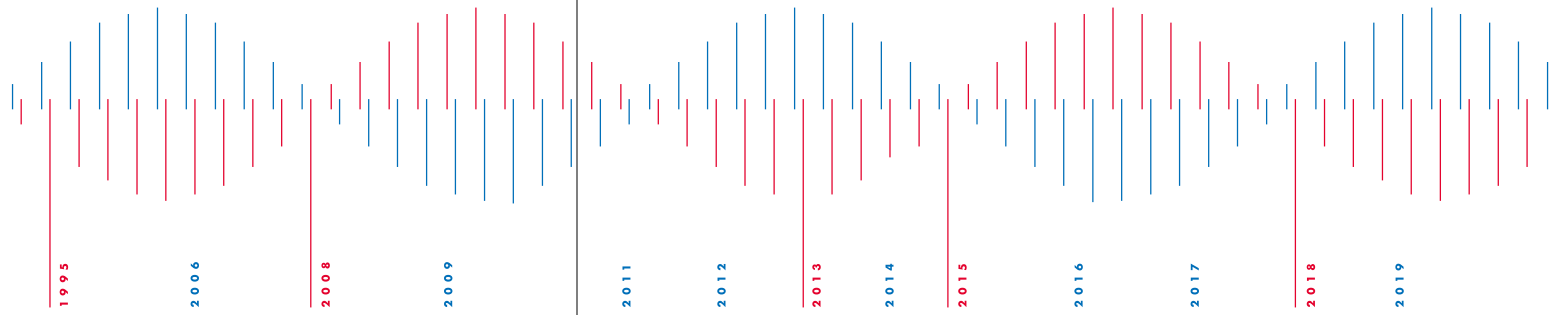
was awarded the 1995 Nobel Prize for Physiology of Medicine together with Edward B Lewis and Eric F. Weischaus for her discoveries concerning the genetic control of early embryonic development. Her research revolutionized our understanding of how animals and their organs evolve and founded a new discipline in molecular genetics – evolutionary molecular developmental biology.

In her work she used QIAGEN's His-tag vector solution among other solutions.

HARALD ZUR HAUSEN

was awarded the 2008 Nobel Prize for Physiology of Medicine for his discovery of human papilloma viruses (HPV) causing cervical cancer. Zur Hausen's findings led to the rollout of routine Pap smear testing in women using diagnostic tests including QIAGEN's careHPV test, and the development of a vaccine against HPV infection.

During his later work investigating the role of the p53 gene in cervical cancer, zur Hausen used extraction solutions including QIAGEN's RNeasy kit.



RANDY W. SHECKMAN

together with James E. Rothman and Thomas C. Südhof was awarded the 2013 Nobel Prize in Physiology of Medicine for his discoveries of machinery regulating vesicle traffic, a major transport system in our cells. These discoveries have had a major impact on our understanding of how cargo is delivered with timing and precision within and outside the cell, disruption of which is implicated in a variety of diseases.

Randy Sheckman used QIAGEN's pool of siRNAs, pEQ-9 and Ni-NTA-agarose in his work.

TOMAS LINDAHL, PAUL MODRICH AND AZIZ SANCAR

were awarded the 2015 Nobel Prize in Chemistry for mechanistic studies of DNA repair. Our DNA molecules are inherently unstable, with defects arising continuously during cell division or in response to damage by UV radiation, free radicals and other carcinogenic substances. The research of Lindahl, Modrich and Sancar described the host of molecular systems that continuously monitor and repair DNA to protect the code of life.

These scientists used the QIAex Gel Extraction Kit and QIAquick PCR Purification Kit among others in their research.

JAMES P. ALLISON AND TASUKU HONJO

were awarded the 2018 Nobel Prize for Physiology of Medicine for their discovery of cancer therapy by inhibition of negative immune regulation. Their findings have inspired efforts around the world to combine different strategies aimed at releasing the brakes on the immune system to eliminate tumor cells even more efficiently. Immune checkpoint therapy is revolutionizing cancer treatment and has fundamentally changed the way we view how cancer can be managed.

Allison and Honjo used QIAGEN's RNeasy Kit, focused qPCR assays and the DNeasy Blood & Tissue Kit in their publications.

…to the next generation of scientists

Today's young scientists are generating ever deeper molecular insights and pushing the boundaries of science to levels that could only have been dreamed of by researchers 30 years ago. QIAGEN is proud to be able to support them in their endeavors. Here we showcase four young scientists, each of them trailblazers in their chosen field of study – perhaps there is even a future Nobel Prize winner in their midst.

ASHA PALAT
PhD candidate at the University of Houston's Department of Biology and Biochemistry

"A lot of my work focuses on understanding how micro RNA is able to suppress tumor metabolism. For that I strongly rely on QIAGEN's RNA extraction kits."

While conventional treatments like chemotherapy can be effective in treating the earliest stages of cancer, they often don't work as well with more advanced disease and many patients don't respond to these treatments at all. Investigating how the tumor microenvironment can be disrupted to starve cancer cells of the nutrients they need to grow and proliferate, Asha Palat aims to develop novel and more humane approaches to fight cancer.

DR. HANNAH WARDILL
Postdoctoral researcher, University Medical Center Groningen

"QIAGEN's CLC provides a really simple way to come in with our 16s data and visualize it very easily. It allows us to assess huge quantities of information in a relatively straightforward and simple manner, which is great."

A person's microbiome affects not only their overall health but also the effectiveness of certain therapies. Dr. Hannah Wardill applies sequencing methods to fecal samples taken from patients before and after chemotherapy treatment to study its impact on the gut microbiome. The ultimate goal of her work is to develop a personalized medicine approach that minimizes toxicities associated with cancer therapies.

DR. DARREN CHOONEEA
Research Scientist, Natural History Museum, London

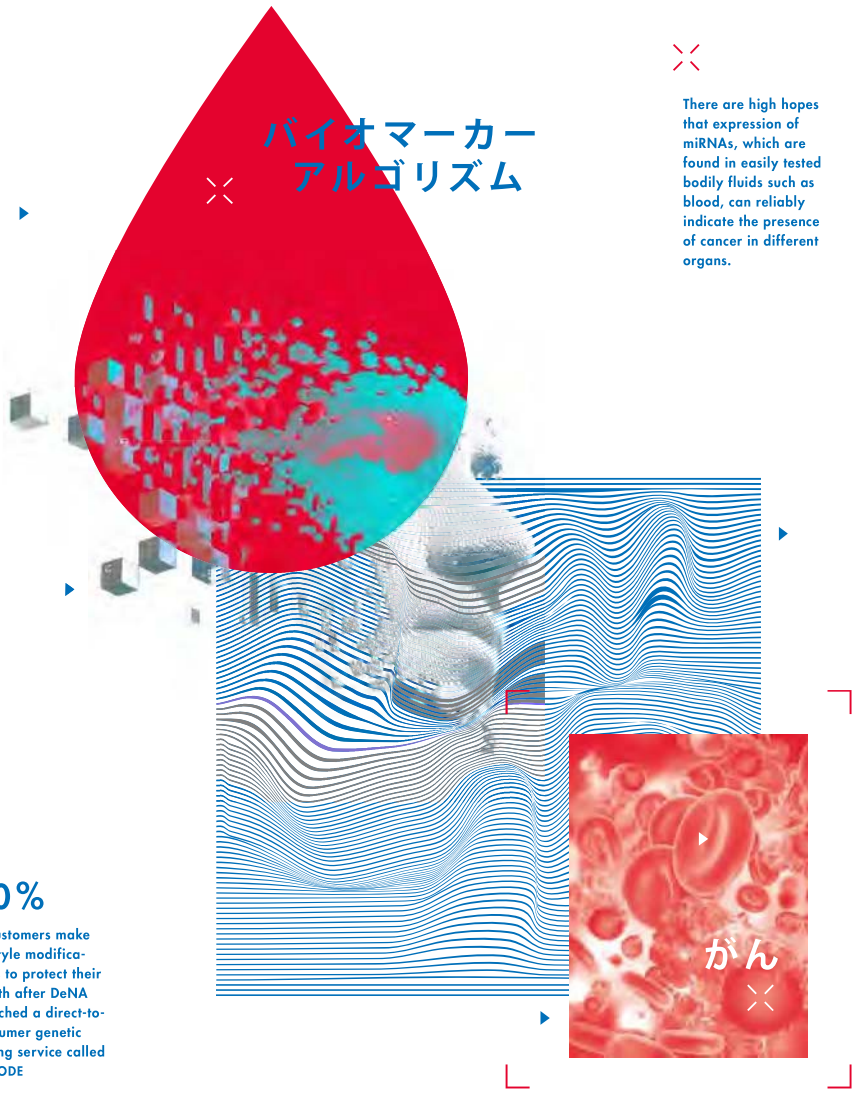
"We have very small amounts of sample material with tiny amounts of DNA output, so we need a whole genome amplification step before sequencing. We use QIAGEN's REPLI-g Ultra-Fast Kit, which is much faster than other solutions available."

The molecular labs of London's Natural History Museum are home to a wealth of fascinating, and often unexpected, research activities. Dr. Darren Chooneea is studying what he describes as the "unseen ecosystem," using DNA sequencing to study the biodiversity of air. Uncovering bacteria, fungal spores, pollen and even human skin, his work has potential applications in monitoring the impact of climate change and early crop pathogen detection.

MORGAN HUGHES
PhD candidate, University of Wolverhampton

"I use the DNeasy Blood & Tissue kits and the QIAamp PowerFecal Pro Kit for species identification from guano collected at key roost sites. I'm fairly new to lab work, as I'm primarily a field biologist, but the QIAGEN kits make it so easy."

UK bat populations have been in constant decline over the last century as building and development have led to mass habitat destruction. In 2018, Ecologist & PhD student Morgan Hughes started the #UrbanBat-Project which aims to catalog bat populations in and around Birmingham, UK, by sequencing samples of DNA extracted from bat guano and mouth swabs. Her goal is to understand the barriers to urban bat dispersal and use this knowledge for conservation efforts.



There are high hopes that expression of miRNAs, which are found in easily tested bodily fluids such as blood, can reliably indicate the presence of cancer in different organs.

90%

of customers make lifestyle modifications to protect their health after DeNA launched a direct-to-consumer genetic testing service called MYCODE

Will deep learning bring about a revolution in cancer diagnosis?

How an e-commerce and gaming giant teamed up with an AI startup to create an innovative, promising solution to fight cancer in Japan.

When Tomoko Namba abruptly announced in 2011 that she was stepping down as CEO of DeNA Co., one of Japan's most successful IT startups, shareholders were shocked. Namba had founded DeNA in 1999 and saw it grow explosively on the back of popular e-commerce and gaming services. She resigned as head of the company to care for her cancer-stricken husband. When he passed away, Namba's commitment to fight cancer was inspirational for another innovative startup that is pioneering a new front in the global battle against the disease.

PFDeNA Inc. was established in 2016 as a partnership between DeNA and Preferred Networks Inc., a Tokyo-based artificial intelligence company founded in 2014 that is now valued at over $2 billion, according to Bloomberg News. The joint venture is harnessing the power of artificial intelligence (AI) to develop a diagnostic system that can identify multiple types of cancer from blood samples, so called liquid biopsy. It's one of the most promising new applications of deep learning, a dynamic AI technique where algorithms learn from massive volumes of data. It's an approach now used in everything from language recognition to self-driving vehicles.

Increased incidence of cancer in an aging population

Cancer is the second leading cause of death globally and accounted for some 9.6 million deaths in 2018, according to the World Health Organization (WHO). As developed countries such as Japan struggle with aging populations and increased incidence of cancer, research shows that AI can detect cancers quickly, helping patients get the care they need.

Dr. Kiyo Ishikura, Associate Director of Healthcare Business, PFDeNA's

A recent Nature study, for example, reported an AI algorithm that can outperform radiologists in the diagnosis of breast cancer, which is plagued by high rates of false positives and negatives. In an editorial, British medical journal The Lancet remarked, "With comprehensive education for our healthcare workforce and openness to AI research in medicine, AI should make an impact sooner than we think."

> "We believe machine learning and deep learning can bring sensitivity and specificity much higher than conventional assays for cancer screening."
> Kiyo Ishikura

Developing these new cancer diagnostic tools is what PFDeNA is all about. Tucked away in a sprawling office complex along the shores of Tokyo Bay, the firm's Harumi Lab is a small and secretive operation. Apart from a simple nameplate on the door, there's nothing that indicates what goes on here. Inside, a corridor lined with large windows reveals a series of labs. Staff use fingerprint scanners to gain access to these spaces. There are automated nucleic acid extraction machines, DNA library construction workstations, and freezers where thousands of patient samples are stored. The company analyzes the samples with next-generation sequencers, looking at global expression paterns of small ribonucleic acids, mainly micro RNAs (miRNAs).

"We believe machine learning and deep learning brings much higher sensitivity and specificity than conventional assays for cancer screening," says Dr. Kiyo Ishikura, associate director of PFDeNA's healthcare business, referring to modern, high-throughput genetic sequencing techniques. "We don't have a traditional bias, and we are proud of our flexibilities with new ideas, and introducing new technologies and methodologies. We try not to set limitations. I believe this mindset comes from the mentality of DeNA."

From hunting biomarkers to pattern recognition

Researchers have long tried to find new biomarkers for cancer diagnostics. However, the community has realized that biological differences in patients means no single biomarker is reliable enough for diagnostics. Staff at PFDeNA and its founding companies are using deep learning to identify common features of miRNA in samples from cancer patients. With anonymized samples from Japan's National Cancer Center, PFDeNA is working to develop assays that can quickly screen for 14 types of cancer, such as prostate, stomach, colon, and esophageal cancer. To do this, the total expression patters for each extracellular RNA (ExRNA) including miRNA are examined. There are high hopes that patterns of miRNA expression, which are found in easily tested bodily fluids such as blood, can reliably indicate the presence of cancer in different organs.

"Since only one or a few such molecules is not enough to differentiate cancer from healthy cells, we're targeting hundreds of different kinds of ExRNA for cancer screening," says Ishikura. "For treatment, knowing you have cancer is not enough. You need to know where. We therefore want to develop a pan-cancer screening assay. Through a single, conventional blood sample, you will know if you have a likelihood of developing cancer as well as the specific cancer type."

An essential tool that staff at PFDeNA are using to build their new screening system is QIAGENs QIAseq kits for next-generation sequencing. These enable researchers to perform differential expression analysis and generate the data that Preferred Networks engineers can use to create deep learning algorithms for pattern recognition.

"QIAGEN is a vital, reliable partner in our work and has provided us with high-quality, cutting-edge reagents and ensured a stable supply," says Tatsuya Yamaguchi, head of lab operations at PFDeNA. "This is very important because it has allowed us to generate the data necessary to bring deep learning and machine learning to bear in this challenge."

"QIAGEN is a vital, reliable partner in our work and has provided us with high-quality, cutting-edge reagents and ensured a stable supply."

Tatsuya Yamaguchi

PFDeNA is working with the Pharmaceuticals and Medical Devices Agency of Japan, which evaluates the safety of pharmaceuticals and medical devices, in order to bring its screening system to the Japanese market in the next few years, and overseas markets following that. It wants to offer a reliable, quick and accurate system that hospitals and other medical centers can use to screen for multiple types of cancer.

Lifestyle modifications to protect health

Ishikura believes PFDeNA has what it takes to succeed, with Preferred Networks' expertise in developing cutting-edge AI solutions, the state-of-the-art Harumi Lab generating quality data, and DeNA's agile decision-making from its long experience in mobile services. After all, in 2014 the mobile giant launched a direct-to-consumer genetic testing service called MYCODE that has seen about 90% of customers make lifestyle modifications to protect their health.

"We will need to challenge not only regulations in the current medical system, but how it fundamentally works – from a 'sickcare' system in which people get sick and then go to hospital to a 'healthcare' system based on preventive diagnosis," says Ishikura. "We believe people will be more driven to maintain good health when much better tools are available to them. Detecting cancer early is an important key to achieving this goal and we believe we can contribute to this."

Tatsya Yamaguchi, Head of lab Operations, PFDeNA

BIOMARKERS

After the WHO-led "International Program on Chemical Safety" biomarkers are defined as "any substance, structure, or process that can be measured in the body or its products and influence or predict the incidence of outcome or disease." In cancer research, biomarkers include numerous molecules that can signal the presence of cancer. For example, prostate-specific antigen is a protein produced by the prostate gland which is used to screen for prostate cancer. Other biomarkers, such as gene mutations, can indicate whether an individual is predisposed to a certain kind of cancer, how the cancer is progressing, or whether treatment is effective. The global biomarker market size is expected to reach USD $118 billion by 2026.

Can we stop the world's deadliest infectious disease?

5,000
deaths each day

>1.5 million
deaths in 2018

10 million
people fall ill with TB each year

3 in 8
individuals go untreated

8 countries
including India, China, Indonesia, the Philippines, Nigeria, South Africa, Pakistan and Bangladesh now constitute more than two-thirds of new TB cases

>1,500
clinical and scientific studies cite the QuantiFERON TB test – which offers the highest accuracy of any test for TB infection

How do we eliminate that disease if one-third of those infected don't know they carry it?

WHO GOALS TO STOP TB

2050
the year that TB should be eliminated worldwide as a public health problem

95%
fewer deaths from TB by 2030

90%
drop in new TB cases by 2030

It's time to end TB!

Dr. Ahmed Raza Jan

The world is zeroing in on ways to eliminate tuberculosis (TB), the world's deadliest infectious disease. Here are three pioneers who, like many others around the globe, are partnering with QIAGEN in their quest to eradicate TB and improve life for its victims.

DR. AHMED RAZA JAN heads the Aziz Medical Center in Islamabad, Pakistan. A family business and the capital's first private clinic, it was founded by his father in 1962 and today plays an important role in the region's fight against a deadly disease. Dr. Jan's tuberculosis screening program sees around 120 children per month and up to 50 applicants seeking visas to the US or Australia each day. These two cohorts, more than any other group, represent the biggest challenge in the fight to eliminate TB in Pakistan: the 5 million cases of latent TB residing there.

Carriers of latent TB infection are asymptomatic and cannot infect those around them. However, left undetected, latent TB can progress into the highly virulent, transmissible and often deadly active form of the disease. TB was responsible for 1.5 million fatalities in 2018, making it the deadliest infectious disease on the planet. While curable in most cases, treatment is lengthy (6–9 months) and is frequently accompanied by debilitating side effects. No one is immune from TB and no country alone can win the war to eradicate it. That's why the United Nations General Assembly, in 2018, held the first-ever high-level international meeting on the fight against TB, themed "United to end tuberculosis: an urgent global response to a global epidemic." By 2030, the World Health Organization (WHO) wants to see new cases drop by 90%. By 2050, that number should fall to zero.

TB spares no one

Whether or not this ambitious goal can be reached depends heavily on nations like Pakistan, one of the eight countries which, together, account for two-thirds of all cases of TB.

The reasons those countries are so affected by this disease are mostly related to socio-economics, believes Dr. Jan: "Overcrowded schools and hospitals are a part of everyday life here. Such conditions provide a perfect environment for the spread of infectious diseases, especially TB. Anyone and everyone in Pakistan is exposed to TB, whether you attend school, step inside a hospital, or simply go shopping. TB spares no one – the disease affects all classes within the population."

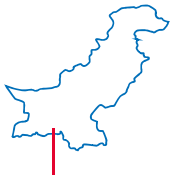
The risk is even higher for children and migrant workers. One in four under the age of 15 in the country are estimated to have latent TB, compared to an estimated 15% of adults. High numbers of untested migrant workers originating in Pakistan, but working all over the world, are also responsible for unknowingly transmitting TB across borders.

New guidelines targeting prevention

"We use x-rays, PCR and QuantiFERON kits to test for latent TB," says Dr. Jan of the clinic's efforts to diagnose the disease. In its Global Tuberculosis Report 2019, the WHO named the QuantiFERON TB Gold-Plus test for diagnosis of latent TB infection in its new guidelines targeting prevention as part of its goal to eradicate TB. Dr. Jan says, "QuantiFERON is a very reliable test and it needs just one visit to the clinic, a large benefit in rural areas, where people often have to travel a long way to the hospital. If we could control latent TB in kids younger than 11, we could massively limit cases of active TB here in Pakistan. And if we could control TB here, where a high number of migrant workers originate, this would inevitably benefit the rest of the world."

That is why, for Dr. Jan, the world should support Pakistan's ongoing battle against TB: "We must screen for latent TB with QuantiFERON, as it is a great test – the only problem is money. People are poor and the health care system runs on a deficit. We have good doctors in Pakistan, just not enough resources. Patients can rarely afford a months-long therapy after testing positive. We lose these people because they believe in fast-acting but ineffective treatments, which only make things worse."

Dr. Jan argues that Pakistan needs funding and international assistance to continue the fight. "It should be like it was in the past, with polio. We have almost eradicated that disease. Now we need to concentrate on doing the same for TB."



PAKISTAN

5th
among TB high-burden countries worldwide

265/100,000
TB rate

61%
of the TB burden in the WHO Eastern Mediterranean Region

QUANTIFERON-TB GOLD PLUS (QFT-PLUS)
is a simple blood test that aids in the detection of Mycobacterium tuberculosis, the bacteria which causes TB. QFT-Plus is an interferon-gamma (IFN-γ) release assay, commonly known as an IGRA, and is a modern alternative to the tuberculin skin test (TST, PPD or Mantoux). Unlike the TST, QFT-Plus is a controlled laboratory test that requires only one patient visit and is unaffected by previous Bacille Calmette-Guérin (BCG) vaccination, which frequently causes false positive skin test results.

Reaching the communities most in need of TB testing

GLOBAL DRUG FACILITY

The Global Drug Facility (GDF), founded in 2001, is the largest global provider of quality-assured TB medicines, diagnostics and laboratory supplies to populations in need. Since its inception, more than $2 billion in TB medicines and diagnostics have been delivered to 142 countries, including over 31 million treatment courses.

In 2019, QuantiFERON®-TB Gold Plus (QFT®-Plus) was added to the diagnostic catalog of the GDF, opening a new channel to reach countries with a high incidence of TB, particularly to areas where QIAGEN has no direct commercial presence. The addition advances QIAGEN's strategy to help expand screening with modern blood-based assays for latent TB infection in regions with a high disease burden but limited resources. QIAGEN supports QFT-Plus accessibility through GDF with additional training and educational programs.

QUANTIFERON ACCESS

In January 2019, QIAGEN announced it was developing a new version of the QuantiFERON-based TB test dedicated and tailored to the needs of low-resource regions of the world with a high TB disease burden. The test, due to launch later this year, will require minimal hands-on time, does not require a laboratory for operation and is compact and portable. Patients will be able to receive a result from a single visit within 24 hours of blood draw.

NIGERIA

6th
among TB high-burden countries worldwide

1st
in Africa with the highest burden of TB

12%
of the global gap between TB incidence and notified cases

108,000
cases notified in 2018

Elom Emeka

TB is the leading cause of infectious disease deaths in Nigeria. The TB epidemic affects mainly younger individuals, aged 15 to 44. As this is notably the most economically productive age group in the country, the burden is significant. Combining the cost of medical service and transport to and from treatment centers with the loss of income makes treating TB expensive. This financial barrier is a major reason why many TB patients delay seeking healthcare. As the African country with the highest disease burden, Nigeria has established a national strategic plan (NSP) for TB control. Elom Emeka, deputy director of medical laboratory services and head of the TB laboratory unit within the Federal Ministry of Health, coordinates the implementation of that plan.

What is the focus in Nigeria's policies for TB control?

ELOM EMEKA TB detection rates are still low in our country. The population needs better access to diagnostic services. That is why we concentrate on equipment maintenance, infrastructure, electricity, human resources and a specimen referral system.

How does the policy help in the fight against TB?

It does so by implementing national guidelines for TB control and innovative diagnostics. In Nigeria, for example, we adopted a latent TB guideline that follows the WHO recommendations. We focus on better identification of at-risk populations like individuals who are HIV-positive and young children to rule out active TB cases, test for latent TB, and then provide and ensure complete treatment. We also monitor adverse events.

Which tools are used in Nigeria to test for latent TB?

Nigeria's Ministry of Health has just approved the adoption and implementation of QuantiFERON®-TB Gold Plus as a modern alternative to the tuberculin skin test. This controlled laboratory test requires only one patient visit, is highly specific and sensitive, and a positive result is strongly predictive of a true infection by M. tuberculosis, whether it is latent infection or active disease. We also require investments in innovations and partnering with national and international organizations to encourage and support resource mobilization and research.

FIGHTING MEANS TESTING

The success of initiatives like the WHO's Stop TB program is highly dependent on effective deployment of treatment and early disease diagnosis. In some regions of the world, health authorities are adopting a blanket treatment strategy for anyone considered to be at high TB risk, without first testing for infection. This approach risks exposing patients to unnecessary treatments with unpleasant side effects, and increases the chances of breeding multidrug-resistant bacterial strains. The rollout of effective testing regimes ensures that only those patients who really need treatment receive it, and allows resources to be deployed efficiently. The key to one day eradicating this disease is finding reliable ways to detect latent TB. Around the world, governments like those in Asia and the Middle East have initiated massive latent TB programs to provide annual testing for millions of at-risk population groups. Oman, for instance, has begun screening approximately two million migrants each year and promises treatment for anyone who tests positive free of charge, without fear of deportation.

UZBEKISTAN

23,000
TB incidence in 2018 (estimated)

70/100,000
TB rate

72%
TB treatment coverage

Timur Abdullaev

OVERCOMING THE STIGMA

Vanquishing TB is about more than just fighting a disease – beyond the toxic activities of microorganisms lie social and educational inequality. TB is perceived as a sickness of the poor, because two-thirds of all new cases arise in developing countries. But TB's impact is global, and can be transmitted to people around the globe, rich or poor.

"TB People" is the very first network of people diagnosed with TB in Eastern Europe and Central Asia. One of its most engaged activists is Timur Abdullaev, a former law consultant specializing in human rights, and based in Uzbekistan. His reason for getting involved in TB activism is easy to explain: Abdullaev was himself diagnosed with the disease, not once, but twice, after suffering its symptoms for several months without being tested for it.

What can a human rights activist do to help the fight to stop TB?

TIMUR ABDULLAEV We connect persons with TB, as well as their relatives, with local activists from our network who know what to do, where to go, and who to get help from. Having suffered from TB themselves, members of our group are hugely empathetic – they know what it is like to have TB, how the person may feel, and what they need. The goal is to mobilize vibrant communities of people infected by TB to fight for their rights.

Is your work connected with health care institutions?

We can serve as a valuable link between clinics and the population. The clinic does not come to the person, the person must go to the clinic. Every year millions of people with latent TB remain undiagnosed worldwide. They are called "time bombs" by others, but those individuals don't know they have TB, that it's just waiting to develop, or that they risk transmitting the disease to others, mainly their loved ones. We fight to grant them access to better diagnostic opportunities.

What do human rights have to do with TB?

Each person has a right to know his or her TB status before receiving a potentially unnecessary medication. The problem is, with TB, a person immediately becomes a patient. A patient is simply someone who is receiving medical services. But there is a fundamental difference between a human and a patient. We stigmatize patients, for instance, when they stop treatment. But the question we should be asking is why the person stopped their treatment. The answer is because the person didn't know any better, or perhaps they weren't given the information or attention they needed.

What kinds of situations have you encountered?

In my region, many TB carriers are migrant workers seeking work in Russia to support their families back in Uzbekistan. Now, what migrant would willingly go to be tested when they know that they will be deported if they test positive? Others suffer from clinical depression, one of a number of difficult side effects caused by the drugs used to treat TB – it is a type of chemotherapy. A patient is not just a patient – they are human beings, and a human being needs to have support, without risk of being discriminated against for their illness.

How can companies like QIAGEN support your work?

We need better diagnostics and better algorithms. We aren't seeking funding from companies, but it could be helpful to, together, apply for funding to start joint projects. And companies must communicate better with their communities. Platforms like the Global TB People Advisory Board enable them to reach out to persons infected with TB. With QIAGEN we started inviting survivors to internal corporate meetings. Many experts at such companies, mostly on the technical side, often never meet any victims of TB. When you establish that personal contact, it can be very motivating – you actually know a person who you've helped through your work.

Human ID

Forensics is no longer about just finding out who has been at a crime scene, but also about what this person has done.

Who did what, and when?

METHODS

SPERM CELLS

64 countries

now have DNA databases used for forensic investigations.

TISSUE SAMPLE

15 seconds

Every 15 seconds a crime sample is processed with QIAGEN chemistry, leading to a match on a database somewhere in the world every 10 minutes.

12 million

people are arrested each year in the United States.

BLOOD SAMPLE

Crime scene in a cell

Modern forensic science goes far beyond solving the mystery of who was present at a crime scene. Using an ever-more sophisticated molecular toolkit, today's forensic investigators are able to build detailed pictures of the perpetrator, from hair and eye color to whether or not they were a smoker, and can even deduce the string of events that took place – all from molecular traces left behind. Here, we present three forensic scientists, each using different molecular methods to answer the same question: which tissue type or body fluid did a biological crime scene sample originate from?

BRUCE MCCORD

1

Epigenetic Insights with Pyrosequencing

PERSON

Bruce McCord, PhD, Florida International University, USA

is Professor of Analytical and Forensic Chemistry and has devoted his career to developing more effective techniques for DNA typing and other forensic applications.

THE CASE

A female homicide victim had a red substance under her fingernails, which was typed and matched to her ex-spouse. If blood, it might indicate foul play; if not it might simply be innocent DNA transfer.

"The big question was whether DNA found under her fingernails and matching to her ex-husband was just touch DNA, innocently transferred when the victim passed their child back to him a few days before the murder, or traces of blood transmitted during a struggle which would implicate her ex-husband in her murder.

Remembering this case, my colleagues and I became interested in the potential of pyrosequencing, a next-generation sequencing technique that can detect epigenetic modifications to the DNA known as differentially methylated regions. As these biomarkers can be human tissue specific, we began investigating pyrosequencing as a method for performing forensic body fluid detection.

We have since developed a number of pyrosequencing procedures built on a variety of QIAGEN kits and tools, including bisulfite modified PCR techniques to identify blood, sperm and other body fluids, an age determination protocol that requires only a single amplicon, and a biomarker for smoking. These methods fit easily into standard forensic laboratory protocols.

Epigenetics

Epigenetics is the study of chemical modifications to DNA which, while not changing the sequence itself, impact DNA structure. Such modifications are essential to gene expression but also can be acquired throughout a person's life in response to external factors including nutrition, temperature and exercise, and enable our cells to adapt to environmental conditions. Epigenetic changes can not only vary from person to person but also can also speciate and affect the function of different cell types in an individual. By using pyrosequencing, such changes can be detected and employed by forensic investigators to identify the tissue type they originated from.

The QIAGEN Pyromark Q48 Autoprep pyrosequencer is automated, which makes it relatively easy for any lab to take our protocols and carry out body fluid identification on their own. The sample extraction process is exactly the same as you'd see in an operational forensic lab for genotyping. You can take a proportion of that same DNA extract used for genotyping and hold it back for body fluid identification, as well as to determine age and whether the suspect is a smoker.

Currently, we are hard at work developing new pyrosequencing protocols to help determine other lifestyle aspects for a DNA profile, including drug abuse and diet.

Using pyrosequencing, we can figure out what kind of DNA was captured and whether it was an innocent contact – or something more nefarious. These insights are all possible by looking at these epigenetic markers.

The ex-husband was eventually convicted of the crime – I testified that the quantity of DNA under the victim's nails was likely too high to be simply touch DNA. The new pyrosequencing techniques we have developed now provide a much higher degree of certainty."

CELIA DÍEZ LÓPEZ

2

Microbiome

PERSON

Celia Díez López, Department of Genetic Identification at Erasmus MC University Medical Center, Rotterdam, the Netherlands

is a PhD candidate from the Department of Genetic Identification. In 2019, Celia Díez López was a finalist for QIAGEN's Microbiome Award

THE CASE

Hypothetical: A woman reports a rape but the suspect claims that he just punched her. Investigators find traces of blood on the bedding. Is it menstrual blood (rape) or nasal blood (violent assault)?

"The microbiome is one of the latest and most promising tools being explored for its use in forensics, although it is not yet ready to be used in investigations.

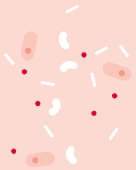
The composition of the microbial community differs not only from person to person but also between different sites on an individual's body. The differences in microbial community between certain body sites are greater than the differences between individuals, and it is this which makes the human microbiome suitable for use in forensic tissue identification. By sequencing microbial biomarkers like the 16S rRNA gene in biological material found at a crime scene, it is possible to assign the microbiome to a particular body part: the microflora in the mouth, on the skin, or on the sexual organs, for example. It can also be possible to deduce whether blood is more likely menstrual or nasal.

There is a lot of potential in the microbiome as a forensic biomarker, but there are still open questions that need to be addressed. Standardization of protocols is needed for evaluation of the huge amounts of data generated and we need to work out how to account for environmental and temporal effects. An individual's microbiome analyzed today will probably show a slightly different composition to one sampled two years ago – this makes it a moving target.

That said, there is a kind of core microbiome, certain populations of bacteria that are body-site specific and present in a high percentage of the population. In our research, we use information retrieved from the entire bacterial community present in a biological sample to deduce where the sample comes from.

We use the Total DNeasy PowerSoil Kit from QIAGEN – it has good protocols and is very user-friendly. Obtaining quality data is imperative, because material gathered at a crime scene is usually, by nature, in limited supply. That means we often only have one attempt available to us, and one that usually comprises an extremely small number of cells.

In forensic work, the microbiome may prove to be an interesting addition to existing technologies and could be used to assign tissue samples to body parts, or to determine the characteristics of a person, such as whether he or she was vegetarian or obese."



Microbiome

The microbiome refers to the genetic material of all of the microbial communities, including bacteria, fungi, protozoa and viruses, which live on and in the human body. With the number of microbes in our body out-numbering human cells by 10 to one, the community composition is unique to each individual and also between different environments on the same person's body, such as the skin, gut and mouth. Sequencing the microbiome has the potential to provide a wealth of information, from placing a person at a crime scene to revealing details of their diet and physique.

MARGREET VAN DEN BERGE

3

RNA sequencing

PERSON

Margreet van den Berge, PhD, Netherlands Forensics Institute, The Hague, Netherlands

is a postdoctoral researcher and was the recipient of QIAGEN's Young Investigator Award in 2019.

THE CASE

Three perpetrators shot at one victim, but only one bullet was fatal. Which of the three fired the lethal shot?

"I like working with RNA. RNA was previously considered to be unusable from a forensic standpoint, because it degraded too quickly. But we now know that tiny snippets of RNA can be extremely long-lived. Even in 20-year-old dried blood samples, we can find RNA of a quantity and quality that can be analyzed. When people think of forensic science, they tend to think of DNA and its use in matching a suspect to a crime scene. Because RNA represents the genes that are expressed in a cell (the transcriptome), and differs between cell types, it can tell us things that DNA can't – such as which body tissue or fluid is present at a crime scene.

We've carried out RNA profiling in more than 300 cases to date. We use two different assays that require RNA strands of less than 150 nucleotides to detect biomarkers for different body fluids and organs. If we're working to solve rape cases, we may assess the presence of body fluids like vaginal mucosa on male samplings. In murder cases, where we need to work out which shot is fatal for example, we focus on identifying which organs a bullet passed through.

In the case of the three shooters, we were able to determine who fired each bullet by working out which bullet originated from which weapon, and then using DNA analysis to connect the weapons to the shooters. A molecular analysis of the RNA from tissue fragments adhering to the bullets allowed us to assign the tissue to a specific organ, because each organ exhibits a unique pattern of gene expression. In this way, we could say whether a bullet passed through, for example, the brain or the heart.

We use QIAGEN multiplex buffers and extraction kits, which provide good results despite the often tiny and highly polluted samples. The lower the quality of the sample, the greater the importance of obtaining a high RNA yield."

mRNA profiling

Messenger RNA (mRNA) is a single-strand RNA molecule that corresponds to the genetic sequence of a gene, and is the representative of the genes that are expressed inside a cell. Because different cells of the human body carry out myriad functions, each cell type will express different genes, and hence the mRNA profiles differ. Profiling of mRNA traces at a crime scene can be used to match the mRNA profile to a cell type.

FACTS ON
CANCER

$1 000 000 000 000

global cancer costs
estimated by WHO
for 2017

50%
estimated growth of cancer burden between 2018 and 2040

10,100,000
new cancer cases in 2000

18,100,000
new cancer cases in 2018

27,000,000
new cancer cases estimated in 2040

1st or 2nd
leading cause of premature mortality in 90 countries

9,600,000
deaths by cancer in 2018

1 in 2
men likely develop the disease in their lifetime

1 in 3
women likely develop the disease in their lifetime

INSIGHTS | PRECISION MEDICINE

FACTS ON
BREAST CANCER

~1 in 8

women in Europe
develop a tumor before
the age of 85

98%
five-year survival rate in cases of localized disease

27%
five-year survival rate in cases of advanced disease

New hope to patients on day one

How a close collaboration helped bring a companion diagnostic to market – the very moment a new breast cancer drug was approved.

Inside a mirrored, multistory building in an office park in Aliso Viejo, an hour's drive from Los Angeles, a small team is hard at work opening a never-ending stream of envelopes and boxes containing blood and tissue samples. They work for NeoGenomics, the U.S.'s largest cancer diagnostic company, routing the incoming samples to one of five different laboratories in the building.

Hundreds of lab technicians work in shifts around the clock, seven days a week, processing the incoming samples through tests ranging from anatomic pathology to cytogenetics and molecular testing. Their mission is to ensure that patients and their physicians get test results as quickly as possible.

"We are here to support the local pathologist or oncologist to provide whatever services they feel they cannot offer in their lab," Dr. Lawrence Weiss, the company's chief medical officer, says. "We offer tests for all cancers and use whichever technology and test will give the patient a reliable result in the shortest time possible." With, on average, 4,000 new cases arriving a day, NeoGenomics performs about one million diagnostic tests in a year. "That volume is staggering, even to me," Weiss admits.

Available by approval

One type of test that NeoGenomics has seen a marked increase in demand for over recent years is a so-called companion diagnostic (CDx) – a test to determine if a patient will benefit from a specific targeted cancer treatment based on the genetic profile of their tumor. Weiss points to the fact that about one-third of all cancer drugs now coming before the FDA for approval are already paired with such companion diagnostics during their clinical trials. Precision medicines like these targeted cancer treatments are transforming patient care by improving patient survival rates and reducing the often debilitating side effects resulting from trial-and-error treatment. For a targeted therapy to be of immediate benefit to a patient, the companion diagnostic needs to

TARGETED CANCER TREATMENTS
also known as precision medicines are "drugs or other substances that interfere with specific molecules to block the growth, progression, and spread of cancer" according to the National Cancer Institute. Unlike conventional chemotherapy whose goal is to kill tumor cells and comes with severe side effects, targeted treatments can take many approaches to more effectively fight tumor cells, such as inhibiting their growth or activating the body's immune system against them. While the FDA has approved 15 targeted cancer therapies, often with drug names ending in "-ib" or "-mab," many more are still in clinical trials.

TIMELINE

2013 – Novartis approaches QIAGEN about developing a companion diagnostic (CDx) for use with their experimental drug, PIQRAY

2015 – QIAGEN starts development work of the *therascreen* PIK3CA companion diagnostic

JULY 2015 – The SOLAR-1 phase III clinical trial starts, using a prototype *therascreen* PIK3CA test to screen for mutations in clinical tissue and plasma samples

"The collaboration between Novartis, QIAGEN and NeoGenomics is a triple win. Most of all, the win is for the patients."

Dr. Lawrence Weiss, Chief Medical Officer, NeoGenomics

DECEMBER 2018 — NeoGenomics, Novartis and QIAGEN start planning for Day-One Readiness for the *therascreen* PIK3CA test

MARCH 2019 — Validation of CDx starts at NeoGenomics

MID-MAY 2019 — Validation completed

MAY 24 2019 — FDA approves PIQRAY and CDx *therascreen* PIK3CA RGQ PCR kit by QIAGEN

MAY 25 2019 — First samples arrive at NeoGenomics facilities for testing

MAY 31 2019 — NeoGenomics starts PIK3CA testing as CDx; submissions run at 200 samples/month

JANUARY 2020 — Submissions for PIK3CA screening increase to 500 samples/month

be available as soon as the drug is announced on the market. Yet in most cases, approval of a test occurs – sometimes months – after a drug is released.

"Companion diagnostics are a very important area to us," Weiss explains, "because there's no point in getting a drug approved and getting patients and the medical community excited if we then have to wait for the diagnostic to be validated." Historically, that could take from a few weeks up to a year. "Being able to do testing right away and offer patients who may be eligible a chance to go on an exciting new drug is a big win for them," says Weiss. "They might have just a few weeks or months to live, and this could be their last chance."

One example he cites of how the companion diagnostic development process should work is the *therascreen* PIK3CA test developed by QIAGEN. The test detects mutations in the PIK3CA gene of patients with advanced or metastatic breast cancer. In this case, the FDA approved both PIQRAY, a novel cancer drug by Novartis, and the QIAGEN diagnostic kit on the same day, in May 2019. This allowed patients to find out in a matter of days if PIQRAY might be the right fit for their specific cancer, and start receiving the potentially lifesaving new drug.

THE PIK3CA GENE
Activating mutations in the PIK3CA gene have long been known to be significant drivers of tumor growth and spread, and are associated with resistance to treatment and a poorer prognosis. They are thought to be present in around 40% of all hormone receptor (HR) +VE / human epidermal growth factor receptor 2 (HER2) -VE cases of advanced breast cancer.

Day-One Lab Readiness

NeoGenomics is one of several companies that have partnered with QIAGEN under its Day-One Lab Readiness program. The program enables diagnostic labs to implement the activities necessary to prepare for the commercial launch of drugs and associated tests before FDA approval is obtained. And as Weiss says: "PIK3CA is the perfect example of how things should be done. All three parties – Novartis, QIAGEN and we here at NeoGenomics – started talking early and were optimally aligned to have the new test validated according to the very rigorous FDA standards." Within just a week of the agency's approval of the drug and the CDx, NeoGenomics was able to offer the new test to physicians and their patients.

"Wouldn't you want to know on day one?"

QIAGEN's Lee-Anne Zinetti on providing peace of mind and proven ability in bringing a companion diagnostic to market.

How does the life of a new companion diagnostic start?
Typically a pharmaceutical company will approach us when they are in the development stages of a new targeted cancer therapy. We work very closely with them on test development, clinical trials and submission of the drug and test to the FDA. In the case of the *therascreen* PIK3CA test, Novartis first approached us in 2013. It took 6 years from then to get to the point of having an FDA-approval in our hands – that's actually pretty fast, believe it or not!

The volume of PIK3CA tests has grown steadily, Weiss says, as he scrolls through a spreadsheet on his computer, from an initial 200 tests a month to thousands of such tests in 2019.

"Having this test available gives hope not only to newly diagnosed patients but also to existing patients who have had few diagnostic and therapeutic options," Weiss says. Since the PIK3CA mutation is generally stable, even biopsies dating back two or three years are often adequate for testing – opening up new avenues for treatment. Under the program, drug maker Novartis is covering the associated costs for testing.

Weiss thinks this speedy and efficient collaboration has set a precedent for future diagnostic tests. From initial talks between the three partners, it took just six months to validate the test and receive final approval. "When you work with the pharmaceutical company and the kit maker early on, it makes things much easier. This model has been so successful, we hope to emulate it in the future." This can have a profound impact on how drugs and associated tests are developed and brought to market.

"It's opened up this whole era of precision medicine. You're no longer prescribing a drug for a whole population with the potential for unwanted side effects, but instead can identify a subset of patients who are most likely to respond," says Weiss. "You can now target a subset of people with the treatment that's optimal for them. Everyone will benefit from this – above all, the patients we want to help."

THE QIAGEN *THERASCREEN* PIK3CA TEST
is a highly sensitive in-vitro PCR assay, suited even for patients who are hard to biopsy or whose biopsies yield insufficient amounts of tissue. Once the NeoGenomics lab receives the tissue sample, it is fixed in paraffin. Lab technicians use a thin slice to isolate patient DNA and mix it with the kit's reagents to check for the presence of specific protein biomarkers, telltale signs of cancerous mutations. A second version of the test works with blood plasma samples. Getting the test results usually takes two to three days. The test is one of seven QIAGEN companion diagnostic to have received FDA approval since 2012.

How does the collaboration under the Day-One program speed up validation?
In the past, validation of a new companion diagnostic has taken up to 12 months post-drug approval – this is hugely frustrating and, in some cases, fatal to patients. Under the Day-One program, we partner with the labs before the approval has been granted. We provide the lab with an early version of the kit while it is being reviewed by the FDA in parallel, and deploy members of our product development and service teams to the Day-One sites to provide rigorous training and support on the new assay.

What does QIAGEN provide to pharmaceutical companies?
QIAGEN provides pharmaceutical partners peace of mind due to our proven ability to bring a companion diagnostic to market with a guaranteed market penetration via access to our global network of Day-One labs.

How do patients ultimately benefit?
If I am an advanced breast cancer patient, I can now get tested to determine my PIK3CA mutation status and find out if I'm eligible for a new treatment option that wasn't available to me before. Wouldn't you want to know on day one?

Lee-Anne Zinetti is Associate Director of Oncology at QIAGEN. She works closely with pharmaceutical and lab partners throughout the complete companion diagnostic development and Day-One Readiness process.

MANIS CULIONENSIS

INSIGHTS | NUCLEIC ACID EXTRACTION

ENDANGERED SPECIES?

END ILLEGAL TRADE OF HOW TO

LIBRARY OF WILDLIFE

Habitat destruction, agricultural intensification and the illegal wildlife trade are just some of the threats to the rich biodiversity of the Philippines. Dr. Ian Kendrich Fontanilla dreams of creating a "genetic archive" of endemic species in the region to guide conservation efforts and turn the tide on mass extinction.

Dr. Ian Kendrich Fontanilla stands in front of the DNA Barcode Laboratory in the University of the Philippines' Institute of Biology. Located in the center of Manila, the university is a stark contrast to the chaotic capital, with halls leading to carefully organized lab rooms, and an inner courtyard graced by tranquil palm trees and flowers that thrive in the tropical climate. The laboratory scene may seem typical, with the standard workbenches, pipettes, test tubes and bottles filling the room, but the lab is full of surprises. Fontanilla's students don their lab coats, turn on their computers, and start retrieving the items unique to this lab from a large refrigerator. Crocodile scales, feathers, tiny skin samples and fragments of bones line the fridge shelves.

Each of these samples tells a story that could eventually reveal the complete picture of the unique and colorful wildlife species in the Philippines. Home to over 52,000 described species, over 50% of which are believed to be endemic, the Philippines is one of 36 defined biodiversity hotspots scattered across the globe. Tragically, deforestation, a burgeoning human population, illegal wildlife trafficking and extreme weather events, also make this one of the world's most threatened hotspots. Recognized as a global conservation priority, numerous wildlife preservation efforts have been initiated across the region, but the lack of knowledge about population structure of the at-threat species poses a challenge to developing management strategies.

DR. IAN KENDRICH FONTANILLA

As a young boy, Dr. Fontanilla wanted to become a medical doctor. He subsequently considered teaching, and then, in college, he discovered he liked to dissect. Ultimately, he studied evolutionary biology and genetics in the Philippines, Japan and the UK. Today he describes himself as a very fulfilled scientist, researching and teaching as head of the Institute of Biology at the University of the Philippines.

Fontanilla is a particularly big fan of the Philippine tarsier, the smallest of its species in the world, whose wide eyes and comically large ears remind him of Star Wars' Yoda. "Today, nobody knows how many, or how few, of this species are left, what their origins are, or the genetic differences between populations in different places," Fontanilla says. In 2008, together with his students, he began an epic task destined to become his life's work: a genetic inventory of all members of the animal and plant world in the Philippines, the various flora and fauna, many of which remain relatively unknown.

Global barcoding community

For his long-term goal to map and archive the entire wildlife in the Philippines, the University of the Philippines participates in BOLD, the Barcode of Life Data System, an international project initiated by the Centre for Biodiversity of Genomics in Canada, to build up a barcode library of all eukaryotic life on Earth. Today, tens of thousands of users in over 100 countries share more than seven million DNA barcodes, all freely available to the research community.

Such data would prove enormously helpful to conservation programs. "Illegal wildlife trade, for instance, could drive animals to extinction before we're even aware of it," Fontanilla says. "Additionally, this data would allow us to better recognize the genetic variances between populations of a species, which would be important information for settlement programs." For example, the populations of the Philippine eagle differ only slightly, genetically speaking, from one another across the country. This is a worrying finding, as genetic variance strengthens a species' ability to adapt and survive, and conservation practices like relocations of this species to other regions would not have any major effect on genetic variance. Another insight of the years-long DNA barcoding project is that the number of species in the regional ecosystems is much higher than initially predicted, and far more invasive species exist than expected.

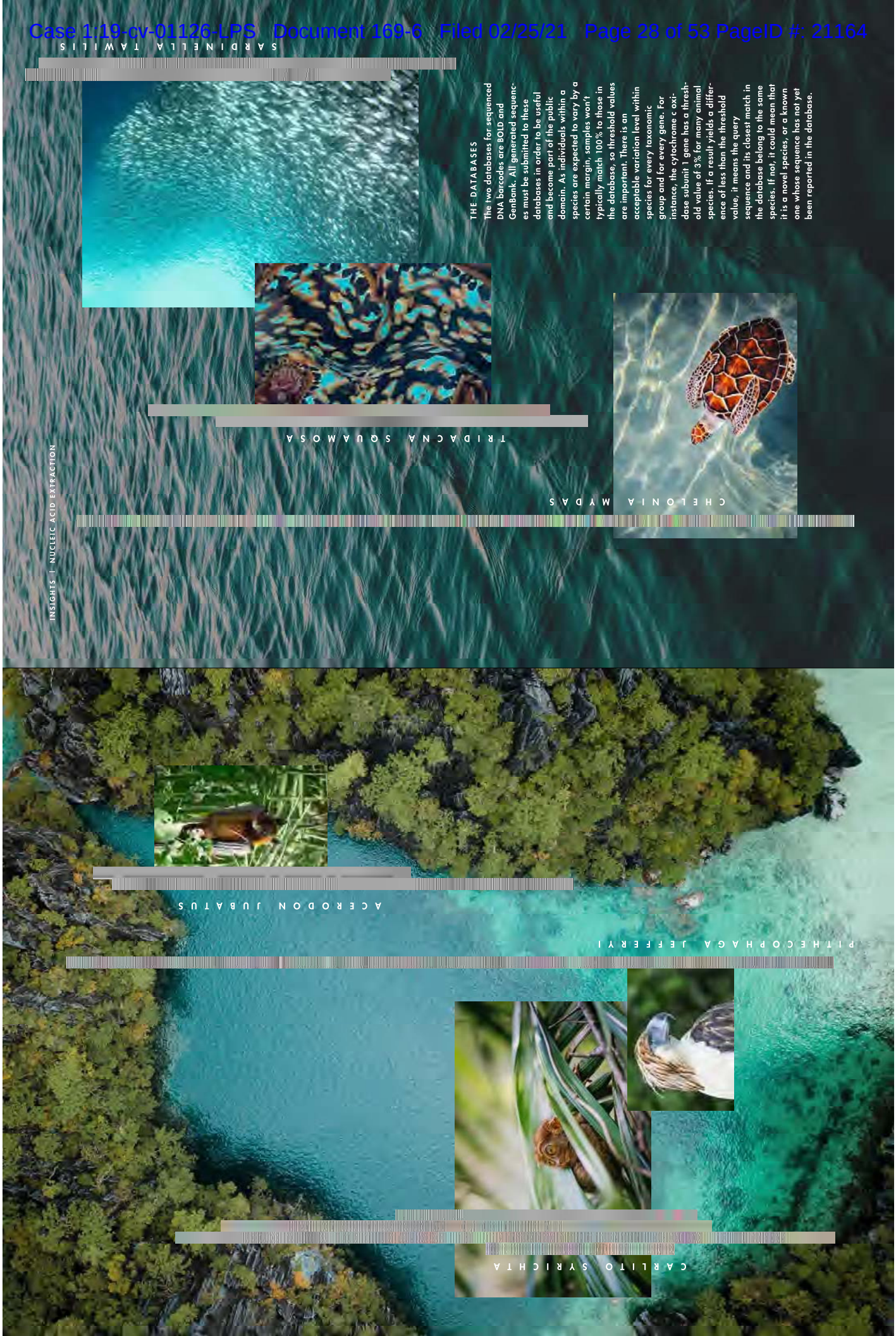
Many of the samples are collected by the students in field studies. "Others we receive from the National Department for Environment and Wildlife," Fontanilla says. "They mostly come from illegally traded, protected wild animals that have been confiscated by authorities."

"Nobody knows how many, or how few, of this species are left, what their origins are, or the genetic differences between populations in different places."

Dr. Ian Kendrich Fontanilla

DNA BARCODE

A DNA barcode is a sequence of DNA nucleotides, a fragment of a gene that should be sufficiently variable across species to distinguish one from another. In most cases, one can distinguish animal species using the cytochrome c oxidase subunit 1 gene, the cytochrome b gene, the 16S ribosomal rRNA gene from the mitochondrial genome, or the 28S rRNA gene from the nuclear genome. Each nucleotide bears a nitrogenous base, which can be adenine, cytosine, guanine, or tyrosine. This sequence of nucleotides provides a unique identifier to a particular species. Each nucleotide, with its specific nitrogenous base, can be represented as a stripe of a particular color. Accordingly, a sequence of nucleotides can be depicted as a barcode of stripes of varying colors.



SARDINELLA TAWILIS

THE DATABASES

The two databases for sequenced DNA barcodes are BOLD and GenBank. All generated sequences must be submitted to these databases in order to be useful and become part of the public domain. As individuals within a species are expected to vary by a certain margin, samples won't typically match 100% to those in the database, so threshold values are important. There is an acceptable variation level within species for every taxonomic group and for every gene. For instance, the cytochrome c oxidase subunit 1 gene has a threshold value of 3% for many animal species. If a result yields a difference of less than the threshold value, it means the query sequence and its closest match in the database belong to the same species. If not, it could mean that it is a novel species, or a known one whose sequence has not yet been reported in the database.

TRIDACNA SQUAMOSA

CHELONIA MYDAS

INSIGHTS | NUCLEIC ACID EXTRACTION

ACERODON JUBATUS

PITHECOPHAGA JEFFERYI

CARLITO SYRICHTA

"Our job is to prove what species they are and, most importantly, where the species comes from," Dr. Fontanilla says, "in order to aid in the conviction of those who trade in such illegal goods."

Barcoding the Philippines

To identify the species, Fontanilla uses the DNA barcode. "Envision this barcode as a single page of a book archived in a library. With the help of experts, one can quickly determine that a particular page comes from Shakespeare, and probably from *Hamlet*."

Translated into molecular biology, the scientist sequences a small section of base pairs which, like a fingerprint, allows conclusions to be drawn about the identity of the species and its origin. This makes the DNA barcode an efficient tool to quickly identify a species, without the need for time-consuming genome sequencing. For example, base pair 951 of the cytochrome c oxidase-1 (CO1) gene indicates a pangolin species, "and pegs its place of origin," he notes.

In 2013, this information was extracted from a pangolin skull confiscated from a Chinese freighter which ran aground on a coral reef off the Philippine coast. In the hold, hidden in a secret compartment, authorities discovered thousands of pangolin carcasses, skinned and significantly decomposed. The rare anteater is another endangered species regularly hunted, since many Asian countries believe it to be a remedy for rheumatism and its meat a delicacy.

"I still remember the sad pictures shown on TV, the incredible number of animals killed," Fontanilla says. Illegal trade has resulted in pangolins becoming nearly extinct in China, Vietnam, Cambodia and Laos. Illegal wildlife trading is punishable by law in the Philippines, but to prosecute, Fontanilla explains, authorities must be able to prove the animals' origin. "In this case, using the DNA barcode, we proved that the pangolins on the Chinese freighter came from the island of Java, Indonesia, where their trade is not outlawed." The arrested crew members were acquitted.

Highest quality from different samples

Gaining these insights is a difficult task for Fontanilla and his team. First, a purely academic project had to be adjusted for practical, forensic application, and second, as Fontanilla says, "We receive a wide variety of samples, like tissue, blood, bone, or even leftovers of a meal found in a kitchen. Often, the material is in poor condition, or we only have tiny amounts of DNA." When these pangolins were discovered, for example, identification was made by taking a smear from the skull. "With luck, we were able to obtain some brain cells from which we could extract genetic information."

QIAGEN's DNeasy Blood & Tissue Kits are used to prepare samples. According to Fontanilla, "It's the best product for extracting sufficient DNA in good quality from a wide variety of degraded samples with very few cells. They are very robust in amplifying the segments, regardless of the quality of the material or the number of cycles, and the many different kinds of samples, from blood to dry tissue, require substantial variation of protocols as well, which QIAGEN also provides."

The DNeasy Blood & Tissue Kit is one of the most versatile in QIAGEN's product line, with optimized protocols and proven quality. "This is another important aspect for us when we have to provide solid evidence in court," says Fontanilla, who has been working with QIAGEN products since 2000, when he completed part of his master's thesis at Nagasaki University. "Ever since then, we have used these kits in our projects because their reputation for high quality means they are widely used, globally."

Even though the DNA barcode project will keep Fontanilla occupied for years, he has an additional goal. "What we would like to begin sequencing the entire genome of the species." For such an ambitious plan, scientists need high-quality specimens, reliable partners like NGOs, and, of course, time. Powerful databases filled with information about the species in the Philippines will help future conservation programs and ensure that rare species, like Ian's beloved Master Yoda, will continue to inhabit forests and not just the archives.

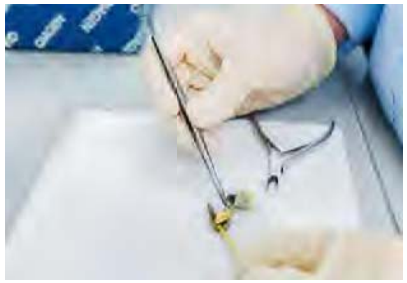
DEVASTATING WILDLIFE TRADE

Wildlife trade threatens the viability of many wildlife populations and, notably, has brought many vertebrate species to the point of extinction. Animals and plants are traded as food, pets or medicine, and the business is organized by large criminal networks, like those trafficking drugs and arms. Interpol estimates that this illegal wildlife trade represents as much as US$20 billion each year. Key markets are China, the US, and the EU. For some animals, the survival rate during transport is a devastating 1 out of every 100.

PANGOLIN

More than 35,000 tons of pangolin, a rare small anteater, are traded worldwide each year, making this endangered species one of the most illegally trafficked in the world. The scales are said to have a healing effect, and the meat is also prized. In China, traders can easily earn several hundred dollars for a single kilogram of the mammal. Catching the pangolin is virtually effortless – the animals curl up in response to danger and are easily collected.

Dr. Fontanilla's lab is home to an array of biological samples. Stored in the refrigerators are crocodile scales, feathers, tiny skin samples and fragments of bone.



QIAGEN's DNeasy Blood & Tissue Kit is Dr. Fontanilla's solution of choice for preparing sensitive samples in his lab.

"An abundance of new applications"

Dr. Jim Huggett, an analytical microbiologist from the National Measurement Laboratory (NML), the UK's designated institute for chemistry and bioanalytical measurements, discusses the importance of standardization – and why the future belongs to digital PCR.

I discovered the importance of standardization first-hand many years ago as a reserach fellow at University College London, working on diagnostics for the developing world. To identify molecular markers of tuberculosis, we were looking at gene expression in patients from different populations who may have contracted the disease. When we measured the RNA in samples from Zambia and Tanzania, we discovered that the results differed between the two labs. It presented us with an important question: Was this discrepancy due to true variation between patient groups, or an artifact due to the different technologies being used in the two labs?

At the time, we were using quantitative PCR (qPCR), and we realized we needed to develop a calibration solution to trust our results. This opened my eyes to a whole field of science I had previously been unaware of: the science of measurement, of standardization, harmonization and measurement accuracy, otherwise known as metrology – a field to which I have dedicated much of my work over the last 10 years.

Today, the use of molecular diagnostics is much more widespread and the methods employed have become more sophisticated. Still, the challenges remain much the same: How can we be sure to get the same result from a diagnostic test in Shanghai as one performed in London? I believe digital PCR (dPCR) holds the answer.

An exact science

Digital PCR is a highly accurate approach for nucleic acid detection and quantification. While the basic principle is the same as other PCR technologies – it involves copying a DNA target of interest millions of times – it differs in that each DNA molecule is partitioned into individual PCR reactions and amplified separately. This means that it is possible to measure absolute numbers of DNA molecules, effectively counting them, something that is not possible with relative methods like qPCR.

I like to use the analogy of analog versus digital radio to explain the key differences between qPCR and dPCR. With an analog radio, you must fine-tune the dial to get the station you want with the least interference. Still, the quality depends on reception and the signal is subject to interference from static. This is qPCR. It is reliable but requires optimization to get a good result, and even then, you must contend with background noise. With digital radio, you simply call up the station and it is either there, with a clear signal, or not.

"dPCR is easy to use and offers an incredibly high level of precision."

JIM HUGGETT

received his doctorate from Cardiff University, in Wales. While at University College London, he worked on improving diagnostics in the developing world by focusing on molecular markers in TB. It was then that he came to appreciate the importance of standardization, realizing that results from one lab could differ significantly from another, even when they used the same technologies and samples. Developing a test that's reliable for use in every country is one of his research goals at LGC, a member of a global network of measurement institutes.

This is like dPCR, which provides precise, binary results. It literally counts the presence or absence of DNA molecules. The clarity of results combined with a low error rate makes for an incredibly high level of precision. dPCR is well suited to measuring smaller quantitative differences.

The precision medicine problem

Precision medicine, in which measurement of rare genetic variants is used to guide cancer therapy, is a great example of where this high level of precision can be useful. In a liquid biopsy, for instance, we are interested in measuring tumor DNA that has made its way into the patient's blood. In addition to tumor DNA, the liquid biopsy contains a lot of the patient's normal genomic DNA. Finding the tiny amount of tumor DNA in the large pool of normal DNA is like looking for a needle in a haystack. The sensitivity of dPCR makes this a perfect method for the detection of this tumor DNA from blood.

Most molecular oncology tests today look at the presence or absence of a tumor variant, but quantitative measures are also valuable. By measuring levels of tumor DNA following cancer treatment, it could be possible to monitor patient response to a drug. Together with national measurement labs across the world, we at the NML, have been investigating the use of dPCR to quantitatively measure tumor DNA. Our results have been incredibly promising. We demonstrated that dPCR can accurately count the number of DNA molecules in a given volume of liquid biopsy, with unprecedented agreement across different laboratories. This opens the door to a whole new level of cancer patient care and also establishes dPCR as the first reference measurement procedure for quantitative DNA measurement. This is incredibly exciting.

We have also used dPCR to quantify RNA molecules, for instance, comparing HIV RNAs to establish a standard for viral-load testing, and we are now applying these methods to explore international standardization of COVID-19 testing. Once again, we have been impressed with the results. Other possible dPCR applications I can foresee are in measuring the efficiency of CRISPR alterations in DNA, or in evading the complications of amniocentesis by performing NIPT dPCR assays.

Of course, this potential is accompanied by a variety of challenges. How can we ensure sample purification methods are standardized? And what thresholds do we set for data analysis? We are working hard to address these. There is also a need for simpler, more affordable instruments to enable labs around the world to harness the power of dPCR technology. But the future is promising, and I can see a day when every lab will have a dPCR instrument and be able to perform highly reproducible quantitative measurements.

And perhaps one day we can truly be sure that a diagnostic test result in Shanghai is the same as one achieved in London.

THE NATIONAL MEASUREMENT LABORATORY

hosted at LGC, delivers underpinning chemical and bio-measurement science for the UK and forms part of the UK National Measurement System (NMS). Research areas span the sectors of advanced therapeutics, diagnostics and safety & security and are delivered through the four core streams of measurement research, calibration facilities, reference materials, and training and consultancy. NML measurement capabilities comprise state-of-the-art mass spectrometry, PCR and cell characterization of products and processes, with many testing and calibration services accredited to ISO/IEC 17025. The NML plays a leading role internationally to develop best practice and standardize measurements across the world.

QIAGEN'S DPCR SOLUTION

Launching in June 2020, QIAGEN's new nanoplate-based digital PCR technology, the QIAcuity, combines the power of partitioning digital PCR with the ease of use of quantitative PCR in a fully integrated system. Partitioning, thermocycling and imaging are all integrated into one automated instrument that takes users from sample to result in less than two hours. With scalable instrument configurations (1-, 4- and 8-plate instruments) it is designed to offer laboratories the highest degree of flexibility in sample throughput. The multi-plate systems will enable higher target multiplexing to increase the amount of information that can be obtained from a sample. Fixed and sealed partitions in different nanoplate configurations, will enable customers to perform high throughput applications like gene expression analysis through to sensitive applications, including copy number variation analysis and rare mutation detection.

The highest standards

Biolab was founded in 2001 with the goal of delivering patient-centered healthcare. Today, with more than 18 labs across Jordan, time and quality are important factors in addressing client needs. With QIAstat-Dx, Biolab found the right answer for these demands and is well prepared to test patients for a likely outbreak of COVID-19.

DR. AMID ABDELNOUR
is the CEO of Biolab. He founded Biolab, with its patient-centered philosophy, in 2001. He is both an influential entrepreneur as well as an expert immunologist.

QIASTAT-DX
The QIAstat-Dx analyzer provides the next generation of syndromic insights. The analyzer, which has won awards for its user interface, utilizes real-time PCR to detect pathogens in human biological samples. This provides clinical laboratories a fast way to simultaneously test for several common pathogens instead of having to rely on a variety of single pathogen tests. Two panels* are currently available for use with the system: The QIAstat-Dx Gastrointestinal Panel offers simultaneous testing for 24 bacterial, viral, and parasitic enteropathogens, while the QIAstat-Dx Respiratory Panel Detects 21 viral and bacterial pathogens.

*Product may not be available in all countries. The QIAstat Gastrointestinal Panel is not cleared for diagnostic use in the U.S.

"A young man from Yemen had been experiencing severe stomachaches and diarrhea for weeks – he was severely ill, but no one could find the cause," says Dr. Amid Abdelnour, founder and CEO of Biolab, describing the first patient diagnosed using the lab's new syndromic testing system, the QIAstat-Dx.

The 14-year-old had fled Yemen with his family to escape the ongoing civil war. They were now at the Jordanian hospital, seeking treatment. In a little over an hour of seeing a doctor, the QIAstat-Dx system presented a set of shocking test results on screen: "The young man tested positive for four pathogens in the QIAstat Gastrointestinal Panal simultaneously – one of which was Vibrio cholerae which causes cholera, a disease that last occured in Amman more than three decades ago," Dr. Abdelnour says.

Multiple previous investigations of the patient had failed to deliver a diagnosis, in part because doctors in Jordan had not expected to encounter a disease that was no longer present within their borders. Fortunately for the Yemeni, the pathogen is included on the QIAstat-Dx Gastrointestinal Panel, along with 23 other enteropathogens. With a clear diagnosis, antibiotic treatment for his specific infection was initiated immediately and he was discharged a few days later. For Abdelnour, the QIAstat-Dx is more than just an automated solution: "What makes QIAstat-Dx special is the ease of use; it's plug and play. And it delivers what doctors want: a quick and reliable result. It's a magic machine."

We meet Abdelnour in the lobby of one of Biolab's Jordan facilities, located in the heart of Amman's hotel and embassy quarter. With 18 labs in Jordan, Biolab is one of the largest medical laboratory chains in the Middle East.

Through the floor-to-ceiling windows in the lobby, patients passing through for tests can see the clinicians and technicians going about their daily work in the labs. Abdelnour says this transparency is important to his work: "The patients should see where and how their samples are being worked, because they are our primary customer."

This patient-centric philosophy was one of the founding principles when he opened the first Biolab facility in 2001. "In our region, it's the patients that come to the lab, not the samples. This requires offering the highest level of comfort and safety. We can't afford any mistakes."

Setting Biolab apart from other clinical labs in the region is the communication of test results not only to the doctors but also directly to the patients. Abdelnour even developed a Biolab app in 2010, which allows patients to easily access their test data and see a graphic display of health-relevant information.

Highest standards. Globally.

But beyond Biolab's emphasis on patient care, Abdelnour also demands reliable and high-quality results. That's why Biolab is one of the few labs in the region with international accreditations from organizations like the College of American Pathologists (CAP) and the International Standards

"We expect to see a new wave of COVID-19, latest in the fall, and then an expanded respiratory panel for the QIAstat-Dx would be a great help to us."

Dr. Amid Abdelnour

"Quality is invisible when applied, but very visible when not."

Lara Sumrain,
Head of Quality Management at Biolab

BIOLAB

is part of one of the largest lab networks in the world, as a member of Integrated Diagnostics Holdings (IDH), listed on the London Stock Exchange. More than four million tests are carried out in 18 laboratories across Jordan.

Organization (ISO). Today, Biolab analyzes samples from Kuwait, Iraq, Dubai, Saudi Arabia, Georgia, and Singapore – with more than 160 labs around the world sending their samples to Amman for testing or confirmation. More than four million tests are carried out in the 18 laboratories. At peak times, his company can process more than 3,000 tests per hour. According to the founder, the key question is how to maintain a high quality despite these high numbers.

"Quality is invisible when applied, but very visible when not," explains Lara Sumrain, head of quality management. Sumrain has been working at Biolab for 14 years. As a medical student, she realized that working in a hospital was not what she wanted to do for the rest of her life. She took an MBA in Quality Management and says, "This work is more in keeping with my character; I'm quite a perfectionist."

Biolab guarantees that tests are carried out to the same quality standards in all laboratories of the group: "Wherever we test a sample, the result should always be the same, regardless of the location and the person doing the test," Sumrain says. She monitors calibration, compliance with standards for Biolab's numerous national and international accreditations, and develops educational training programs for personnel.

When it comes to quality, she praises the QIAstat-Dx: "This technology is not just fast but also easy to use. Real-time PCR is a highly precise technology; it requires hardly any maintenance, fewer steps and less hands-on time, which means fewer chances of mistakes."

READY FOR THE NOVEL CORONAVIRUS

Declared a pandemic by the World Health Organization, this novel coronavirus leads to an infection with symptoms including fever, cough, and shortness of breath. There are now more than 2.5 million confirmed cases across the globe, with more expected. In Amman, as everywhere else, the topic of coronavirus is on everyone's lips. At the time of writing, there had been 428 confirmed cases in Jordan, and higher numbers in the surrounding countries, including the West Bank, Egypt, and Iraq.

Najwa Saediddeen, a young lab technician working at one of Jordan's Biolab facilities, sees a huge value of the QIAstat-Dx syndromic testing device for screening in epidemics, and is eagerly awaiting QIAGEN's new QIAstat-Dx Respiratory SARS-CoV-2 Panel, which includes a test for the SARS-CoV-2 virus which causes COVID-19. "There are already several forms of coronaviruses in the existing QIAstat-Dx Respiratory Panel," she says. "The new panel, including SARS-CoV-2, will be very valuable in the likely event of an outbreak here, in Amman."

Dr. Amid Abdelnour believes there will be a new wave of SARS-CoV-2 in the fall – and the new QIAstat-Dx panel that includes the SARS-CoV-2 virus will be a great help in containing the disease. "Single tests would only provide a yes or no result. But even if a test is negative for corona, doctors and patients still want to know what it is, instead," he says, "so they can choose the appropriate treatment." He doubts that this will be possible with other single tests for coronavirus infections. For him, the combination of quality and speed could help Biolab stand ready in the event of an outbreak in the region, while also continuing to make sure patients receive the care they need.

QIASTAT-DX RESPIRATORY SARS-COV-2 PANEL

In response to the COVID-19 pandemic, QIAGEN has developed the QIAstat-Dx Respiratory-SARS-CoV-2 Panel. The new panel was launched as a CE-IVD product in Europe and other regions, including Jordan in March 2020. The panel detects the SARS-CoV-2 virus and can differentiate from 21 other targets implicated in acute respiratory syndromes. The test works by targeting two genes: ORF1b and the E gene from the SARS-CoV-2 virus.

The QIAGEN Knowledge Base

>20 years of data curation

>200 PhDs and MDs manually curating all information

>40 public and proprietary databases contributing data

Information from: scientific publications, clinical trial data, drug label information

20 million+ curated findings in total

5,000+ new data findings per day

90,000 users worldwide

>1.6 million patient tests analyzed

INSIGHTS | BIOINFORMATICS

QIAGEN CLINICAL INSIGHT (QCI) INTERPRET

QCI Interpret is bioinformatics software for interpretation of clinical next-generation sequencing (NGS) data. The software interrogates genetic mutations identified in an earlier genomic analysis step against a vast database known as the QIAGEN Knowledge Base, which holds over 20 million curated findings. The report generated by the software includes all of the information needed by the clinician to determine which genetic aberrations play a role in the patient's disease. Information about clinical trials and drugs recommended for targeting the mutations is also provided.

Dr. Sehime Gülsün Temel relies on QIAGEN's bioinformatics tools to help her understand the mechanisms underlying rare diseases.

Putting the pieces of the puzzle together

Dr. Sehime Gülsün Temel, the dark-haired, soft-spoken head of the Translational Medicine Department at Uludag University in Bursa, Turkey, appreciates the challenge of solving mysteries. When it came time to choose a career path, doing genetic work to understand the molecular mechanisms underlying rare diseases felt like an obvious fit.

"It's like mathematics, or a puzzle," she says. "You are given the different pieces to fit together to explain why or how a patient develops a particular medical condition. It is fascinating work."

She has spent the bulk of her career trying to piece together genetic puzzles to understand different cancers, as well as conditions like osteogenesis imperfecta, better known as brittle bone disease, and sudden cardiac death, the abrupt and unexpected loss of heart function. She likens the work to looking for a single precise fish in a vast ocean. But like any good fisherman, instinct can only take her so far. To catch the right fish, she needs good bioinformatics tools to assist her.

Genetic targets for future therapies

"We have between 20,000 and 25,000 genes. Can you imagine?" Dr. Temel asks. "And within all these genes, there are a multitude of variants. Trying to find the precise gene or mutation, that exact reason for a rare disease, is not easy." And that is the challenge she likes. Together with her colleagues, she often works with limited samples because of the rarity of such cases. But still they persevere in their attempts to develop new diagnostic tools for these rare conditions, as well as identify genetic targets that could be used for future therapies.

Her team is currently working to elucidate the genetic underpinning of rare congenital connective tissue disorders, including Arterial Tortuosity Syndrome (ATS). ATS is a rare autosomal recessive disorder, characterized by twisting and distortion (tortuosity) and elongation of the large- and medium-sized arteries. Approximately 200 cases of ATS have been reported in the literature to date, but for those few sufferers the disease can be debilitating and lead to life-threatening aneurysms, strokes, and heart failure.

It is the kind of puzzle that Dr. Temel is drawn to – and her work, together with colleagues from across the globe, on the underlying genetic causes of these rare connective tissue disorders has led to new information about connective tissue and related fibers that may help patients to find a cure in the near future.

She and her team used exome sequencing on nearly 5,000 targets to find potential genetic culprits that might explain the unique phenotypes exhibited in different rare connective tissue disorders. But without QIAGEN's bioinformatics tools, she would be unable to sift through the genome's vast ocean to find the tiny rare fish she needs in order to understand what genetic abnormalities have led to its features.

"QIAGEN products, in general, are very user-friendly and produce quality results," she says. "But the bioinformatics tool is the most important to my work. We use QCI Interpret, which allows us to filter variants very quickly, in just a matter of a few hours. It is very useful to help find the exact variants we are looking for to better understand a disease."

Temel says she is driven to help patients with rare diseases who may be misdiagnosed due to a lack of the right diagnostic tools. And, too often, they have little or no effective therapies to help them manage their conditions. "If we can find the right biomarkers, if we can use big data techniques to go through all this genetic information and find what we need, we can then find a treatment," she says. Many rare diseases leave unique molecular calling cards that doctors can use to help them make the right diagnosis. "The more we can understand what is in this data, the more we can offer in terms of precision medicine for individual cases, even in these very rare disorders."

ULUDAG UNIVERSITY

Located in Bursa, Turkey, about 150 kilometers south of Istanbul, across the Sea of Marmara, Uludag University is one of the country's most prolific research institutions. Established in 1975, Uludag University has more than 45,000 students with specialties in medicine, engineering, and social sciences.

RARE DISEASES

A rare disease is defined as a condition that affects fewer than 1 in 2,000 people. To date, scientists have identified more than 6,000 rare conditions, although there are likely many more, and together, they affect tens of millions of patients worldwide. While there are many causes of rare disease, the vast majority are thought to be genetic in nature. As such, genetic studies are medicine's greatest hope for coming up with new diagnostic tools, as well as targeted treatments for these conditions.

ATS

Arterial tortuosity syndrome (ATS) is a rare, autosomal recessive connective tissue disorder linked to mutations in the SLC2A10 gene. This mutation results in malformations of major blood vessels, including the aorta. With no dedicated treatments, most who receive this diagnosis won't live to see adulthood.

ATS is a remarkably rare disorder, affecting fewer than 200 people across the globe. Dr. Temel, and colleagues, published an article in *Genetics in Medicine* in 2018 which looked at the genetic profiles and clinical dispositions of 40 families with a history of ATS.

QIAGEN'S BIOINFORMATICS TOOLS

expertly curate both clinical and genetic information to form actionable insights. Those who study rare disorders are often limited by the number of patients and available genetic samples. In using QIAGEN's bioinformatics tools, which allow them to connect and collaborate with scientists all over the globe, they are better equipped to discover novel mutations that underlie rare diseases.

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TRADEMARKS

In this annual report QIAGEN uses the term molecular diagnostics. The use of this term is in reference to certain countries, such as the United States, and limited to products subject to regulatory requirements.

As of February 2020, QIAGEN molecular diagnostics products included 23 FDA (PMA approved or 510k cleared) products, 17 clinical sample concentrator products (14 kits and 3 instruments), 66 EU CE IVD assays, 17 EU CE IVD sample preparation products, 17 EU CE IVD instruments for sample purification or detection, 34 China CFDA IVD assays/sample preparations and 9 China CFDA IVD instruments.

This annual report may also contain trade names or trademarks of companies other than QIAGEN.

SAMPLE TO INSIGHT

The molecular revolution
A scientific revolution is rapidly evolving our understanding of DNA and RNA – the building blocks of life. It's affecting us in ways we don't even realize.

The challenge
Gaining access to valuable molecular insights – and understanding their impact – remains elusive and challenging.

THAT'S WHY QIAGEN EXISTS

Every day we help more than 500,000 customers gain the valuable molecular insights they need

HOW WE DO IT

Offer a targeted product portfolio to enable insights from samples for virtually any application involving the building blocks of life.

Keep a finger on the pulse of innovation to turn the latest scientific breakthroughs into useful products.

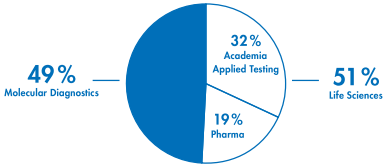
Bring together 5,000 passionate QIAGENers who are driven by the impact of their work and to excel in helping customers exceed their own expectations.

Extend our global reach so we're everywhere our customers are – in countries around the world and even in space.

MAKING IMPROVEMENTS IN LIFE POSSIBLE

OUR COMPANY

Customer Classes
share of 2019 net sales



Product Categories
share of 2019 net sales

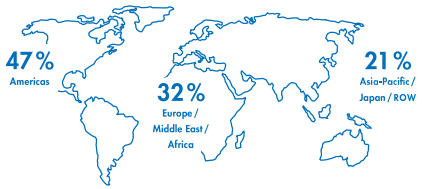
13%

Instruments
are used with consumables, enabling customers to automate processes from the preparation of clinical samples to the delivery of valuable results.

87%

Consumables and related products
are specialized kits that contain all necessary materials to support the use of sample and/or assay technologies as well as bioinformatics solutions for analysis, interpretation and reporting of biological data.

Global Presence
of total QIAGEN sales



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TRADEMARKS

Our name together with our logo is registered as a trademark in the United States and a number of other countries: QIAGEN®.
For a complete list of QIAGEN's trademarks and disclaimers, please refer to QIAGEN's webpage under www.QIAGEN.com/trademarks_disclaimers.aspx.

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QIAGEN ALLIANCE

Exhibit 95

SEP 17 2018

QIAGEN and NeuMoDx announce strategic partnership to offer next-generation systems for fully integrated molecular diagnostic testing

QIAGEN to launch two Sample to Insight systems in Europe and other markets, NeuMoDx to commercialize in the U.S. / Initial assay menu for infectious diseases and LDTs

Hilden, Germany, and Ann Arbor, Michigan, September 17, 2018 – QIAGEN N.V. (NYSE: QGEN; Frankfurt Prime Standard: QIA) and NeuMoDx Molecular, Inc. today announced a strategic partnership to commercialize two new fully integrated systems for automation of PCR (polymerase chain reaction) testing. These next-generation systems are specifically designed to help clinical molecular diagnostic laboratories process increasing test volumes and deliver more rapid insights on a broad range of diseases.

Under the agreement, QIAGEN will initially distribute the NeuMoDx™ 288 (high-throughput version) and NeuMoDx™ 96 (mid-throughput version) in Europe and other major markets worldwide outside of the United States. NeuMoDx will cover the United States directly. Additionally, the companies are collaborating to implement certain QIAGEN chemistries on the NeuMoDx systems. The two companies have also entered into a merger agreement under which QIAGEN can acquire all NeuMoDx shares not currently owned by QIAGEN at a predetermined price of approximately $234 million (QIAGEN currently owns about 19.9% of NeuMoDx), subject to the achievement of certain regulatory and operational milestones.

QIAGEN intends to begin commercialization of the NeuMoDx systems at the European Society of Clinical Virology (ESCV) congress (September 23-26 in Athens, Greece) with an initial assay menu based on the first two CE-IVD marked assays for Group B *Streptococcus* (GBS) and *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/NG) infections. The NeuMoDx systems offer a growing menu of relevant in vitro diagnostic (IVD) tests and the ability to process both commercial and laboratory-developed tests (LDTs) in the most flexible and efficient manner. LDTs, which account for

an important number of test requests and volumes, are IVD tests designed by clinical labs for their own use.

"Molecular diagnostic labs are demanding a true next generation of solutions for molecular diagnostic testing with features such as full automation, fast turnaround time, scalability, cost efficiency and ease of use," said Peer M. Schatz, Chief Executive Officer of QIAGEN N.V. "The NeuMoDx approach delivers on this promise to customers with simpler and much faster workflows on more compact and versatile systems. It brings the simplicity of established clinical chemistry automation to molecular diagnostics along with rapid turnaround time in about 40 minutes and promises massive sample processing capacity and a broad menu of tests. Together with QIAsymphony, QIAstat-Dx and GeneReader, the addition of NeuMoDx will enable QIAGEN to offer complementary systems that create an unparalleled portfolio of platforms for molecular diagnostics labs worldwide – addressing all key segments. We are determined to expand on our leadership position by offering solutions for use in every molecular diagnostics laboratory worldwide."

"We are excited about joining forces with QIAGEN to take NeuMoDx to the next level on a global basis. These revolutionary new solutions for molecular diagnostics, along with a rich menu of tests under development, will deliver real benefits to central laboratories, hospitals and the patients they serve," said Jeff Williams, Chairman and Chief Executive Officer of NeuMoDx Molecular. "This agreement with QIAGEN is an important recognition of the excellence of our NeuMoDx team, our achievements in developing the platform and the work we continue to do. We begin this collaboration by launching the NeuMoDx systems and initial assays, and the relationship will deepen as we achieve additional development and commercialization milestones."

The NeuMoDx systems possess many key features that differentiate them from other laboratory-based PCR diagnostics systems. Most importantly, the NeuMoDx systems have the distinction of fully integrated operation, including performing every step from sample extraction through detection and results reporting. The addition of these systems strengthens QIAGEN's portfolio of molecular testing platforms to address laboratory needs in almost any setting for molecular diagnostics.

- **Rapid access to insights:** The NeuMoDx 288 and 96 systems offer a unique combination of speed, flexibility, throughput and ease of use. Melding high-throughput specimen processing capabilities with the industry's fastest fully automated turnaround time produces insights in about 40 minutes compared to competing systems requiring more than three hours. With up to 42 patient specimens processed per hour, the relatively compact NeuMoDx 288 offers higher levels of throughput than almost any other system. Laboratories' ability to report results back to ordering physicians more comprehensively and in a much shorter period of time will be greatly enhanced, thereby enabling faster treatment decisions and better outcomes. The speed of the NeuMoDx systems is derived from many fundamental innovations such as patented extraction technologies, advanced microfluidics and silicon technology-based thermal cycling. Both

systems can be fully integrated into LIMS (laboratory information management systems) for efficient handling of results.

- **Broad menu with continuous and true random access:** Both platforms allow for continuous loading of specimens with true random access available for the first time in an integrated system. Laboratories can continue testing even when a lab worker loads additional specimens for use with different tests. The NeuMoDx 288 holds all the reagents required for up to 30 different assays on board, while the NeuMoDx 96 can accommodate up to 20 different tests. The systems offer unlimited access to process both commercial and LDTs for up to 288 preloaded specimens for the NeuMoDx 288 and up to 96 specimens for the NeuMoDx 96, providing a walkaway time of between 5 and 8 hours. The breadth of menu and the market-leading ease of use for conducting LDTs allow laboratories to consolidate all their testing needs onto a NeuMoDx platform. The two initial CE-IVD marked commercial assays focus on high-volume tests – the NeuMoDx™ CT/NG Assay for detection of the sexually transmitted *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections and the NeuMoDx™ GBS Assay for detection of Group B *Streptococcus,* a leading cause of life-threatening bacterial infections in newborn babies. A full menu for detection and monitoring of various diseases is under development, with many new assays to be launched in the coming months.
- **Best-in-class workflow:** The NeuMoDx 288 and 96 platforms are designed to address the widest range of customer needs among clinical laboratories by addressing specific throughput and lab space requirements. The NeuMoDx 96 requires less lab space than even the smallest instrument that is currently available for the same target applications and throughput, and the NeuMoDx 288 is about 2-4 times smaller than direct competitors with the same or higher throughput. All NeuMoDx systems use identical consumables and the same core technology, offering laboratories significant advantages in cost efficiency and ease of use compared to other systems. No reagent preparation is required, and onboard reagents are stored at room temperature for up to two months inside the system. The NeuMoDx systems have been designed for performance and cost leadership with features such as generic cartridges for universal nucleic acid extraction and PCR detection for all sample types and tests, and proprietary NeuDry™ dehydrated reagents that reduce waste and extend storage life.
- **Strengthening QIAGEN's Sample to Insight portfolio:** NeuMoDx significantly strengthens QIAGEN's portfolio of molecular diagnostic platforms. QIAGEN now has the ability to address the needs of any clinical laboratory worldwide – regardless of test volume processing requirements – with solutions using PCR or next-generation sequencing (NGS). In addition to the NeuMoDx systems for fully integrated PCR testing, QIAGEN offers these solutions:
    - *QIAsymphony*: The No.1 automation solution for processing samples for nucleic acid extraction from a broad range of samples (including blood, liquid biopsy, tissue, etc.) for use in PCR, NGS and other detection applications. In connection with the Rotor-Gene Q PCR, QIAsymphony is a leading modular platform that allows the highest level of flexibility in processing both commercial assays and LDTs.

- *QIAstat-Dx*: The next generation in one-step multiplex molecular diagnostic systems that enable fast, cost-effective and flexible syndromic testing with novel Sample to Insight solutions based on PCR technology. Launched in 2018 in Europe, and planned for U.S. launch in 2019, QIAstat-Dx addresses the needs of clinical laboratories for near-patient testing for a range of conditions and helps reduce diagnostic uncertainty.
- *GeneReader NGS System:* The first truly complete Sample to Insight next-generation sequencing (NGS) solution designed for any laboratory to deliver actionable results.

About NeuMoDx

NeuMoDx Molecular, based in Ann Arbor, Michigan, designs and develops revolutionary molecular diagnostic solutions for hospital and clinical reference laboratories. Its patented platforms offer market-leading ease of use, true continuous random-access, and rapid turnaround time while achieving optimal operational and clinical performance for our customers and the patients they serve. For more information visit www.neumodx.com.

About QIAGEN

QIAGEN N.V., a Netherlands-based holding company, is the leading global provider of Sample to Insight solutions that enable customers to gain valuable molecular insights from samples containing the building blocks of life. Our sample technologies isolate and process DNA, RNA and proteins from blood, tissue and other materials. Assay technologies make these biomolecules visible and ready for analysis. Bioinformatics software and knowledge bases interpret data to report relevant, actionable insights. Automation solutions tie these together in seamless and cost-effective workflows. QIAGEN provides solutions to more than 500,000 customers around the world in Molecular Diagnostics (human healthcare), Applied Testing (primarily forensics), Pharma (pharma and biotech companies) and Academia (life sciences research). As of June 30, 2018, QIAGEN employed approximately 4,800 people in over 35 locations worldwide. Further information can be found at http://www.qiagen.com.

Forward-Looking Statement

Certain statements contained in this press release may be considered forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, and Section 21E of the U.S. Securities Exchange Act of 1934, as amended. To the extent that any of the statements contained herein relating to QIAGEN's products, collaborations markets, strategy or operating results, including without limitation its expected adjusted net sales and adjusted diluted earnings results, are forward-looking, such statements are based on current expectations and assumptions that involve a number of uncertainties and risks. Such uncertainties and risks include, but are not limited to, risks associated with management of growth and international operations (including the effects of currency fluctuations, regulatory processes and dependence on logistics), variability of operating results and allocations between customer classes, the commercial development of markets for our

products to customers in academia, pharma, applied testing and molecular diagnostics; changing relationships with customers, suppliers and strategic partners; competition; rapid or unexpected changes in technologies; fluctuations in demand for QIAGEN's products (including fluctuations due to general economic conditions, the level and timing of customers' funding, budgets and other factors); our ability to obtain regulatory approval of our products; difficulties in successfully adapting QIAGEN's products to integrated solutions and producing such products; the ability of QIAGEN to identify and develop new products and to differentiate and protect our products from competitors' products; market acceptance of QIAGEN's new products and the integration of acquired technologies and businesses. For further information, please refer to the discussions in reports that QIAGEN has filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC).

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Exhibit 96

SEP 17 2020

QIAGEN fully acquires NeuMoDx Molecular, Inc., rounding out portfolio of PCR-based diagnostic automation systems

- Transaction strengthens QIAGEN's leadership position in automated molecular testing
- QIAGEN acquires remaining 80.1% stake in NeuMoDx Molecular, Inc. for $248 million
- Medium- and high-throughput NeuMoDx automation solutions based on PCR testing technology to now be integrated into QIAGEN's portfolio on a global basis
- Menu of test solutions for infectious diseases – which already includes COVID-19 – to be expanded, especially in the U.S.

Hilden, Germany and Ann Arbor, Michigan, September 17, 2020 – QIAGEN N.V. (NYSE: QGEN; Frankfurt Prime Standard: QIA) today announced the acquisition of the remaining 80.1% of diagnostics instruments company NeuMoDx Molecular, Inc. for $248 million in cash. The move rounds out QIAGEN's portfolio of automated molecular testing solutions based on the proven PCR technology.

The transaction was completed after QIAGEN received U.S. regulatory clearance for the full acquisition. In 2018, QIAGEN had purchased a 19.9% stake in NeuMoDx along with the right to acquire the remaining NeuMoDx stake at a price of $234 million. The final payment price for this remaining stake includes customary purchase price adjustments for cash, indebtedness and transaction costs. Also as part of the 2018 agreement, QIAGEN has distributed the high-throughput NeuMoDx™ 288 and the medium-throughput NeuMoDx™ 96 platforms in Europe and other markets outside the U.S.

"NeuMoDx's automated molecular testing platforms offer a unique combination of speed, flexibility, throughput and ease of use for molecular diagnostics assays, including laboratory-developed tests," said Thierry Bernard, Chief Executive Officer of QIAGEN. "NeuMoDx has built an unparalleled platform that has demonstrated superior value during the coronavirus pandemic. This will expand QIAGEN's portfolio of automated testing solutions and provide another driver for future growth."

"NeuMoDx devices offer labs with medium to high throughput exactly what they need," Bernard added. "Labs want compact systems with true random access, fast turnaround time, full automation and comprehensive menus. The full integration of the NeuMoDx systems will allow QIAGEN to address laboratory needs in almost any setting for molecular diagnostics. We are excited to be able to build on NeuMoDx's success and will jointly work on expanding our product portfolio and global distribution."

"Becoming a part of QIAGEN allows us to take our successes at NeuMoDx to the next level," said Jeff Williams, Chairman and Chief Executive Officer of NeuMoDx Molecular. "We have built a broad testing portfolio and created strong customer enthusiasm around the world with our device's unique combination of speed, flexibility, throughput and ease of use. This transaction is a testament to the achievements of the entire NeuMoDx team and we are excited to finally become a full part of the QIAGEN family."

As rapid, integrated PCR-based devices, NeuMoDx™ 288 and NeuMoDx™ 96 already offer 13 CE-IVD-marked assays for different infectious diseases in Europe. These include a dedicated COVID-19 test, which has also received FDA Emergency Use Authorization for the U.S. market, complementing the FDA-approved GBS assay (group B Streptococcus). A new multiplex test for influenza, respiratory syncytial virus (RSV) and the SARS-CoV-2 virus is scheduled for launch in the fourth quarter of 2020.

The NeuMoDx devices have features that set them apart from other lab-based PCR diagnostics systems: they have the fastest fully automated turnaround time, delivering insights in an hour rather than their competitors' three hours; they allow clinical molecular diagnostic laboratories to process ever-larger volumes and deliver ever-faster insights into many infectious diseases including COVID-19; their flexibility and efficiency is driving a growing menu of in vitro diagnostic (IVD) tests and enables the devices to process commercial and laboratory-developed tests (LDTs – IVD tests made by clinical labs for in-house use).

QIAGEN plans to provide further information on the financial impact of this transaction when it reports results for the third quarter and first nine months of 2020 in early November 2020.

For more information about NeuMoDx systems and current assay menu please visit qiagen.com/neumodx.

Further information on QIAGEN's response to the coronavirus outbreak can be found here.

About NeuMoDx

NeuMoDx Molecular designs and develops revolutionary molecular diagnostic solutions for hospital and clinical reference laboratories. The company's patented, 'sample-to-result' platform offers market-leading ease of use, true continuous random-access, and rapid turnaround time while achieving optimal operational and clinical performance for our customers and the patients they serve. For more information visit www.neumodx.com.

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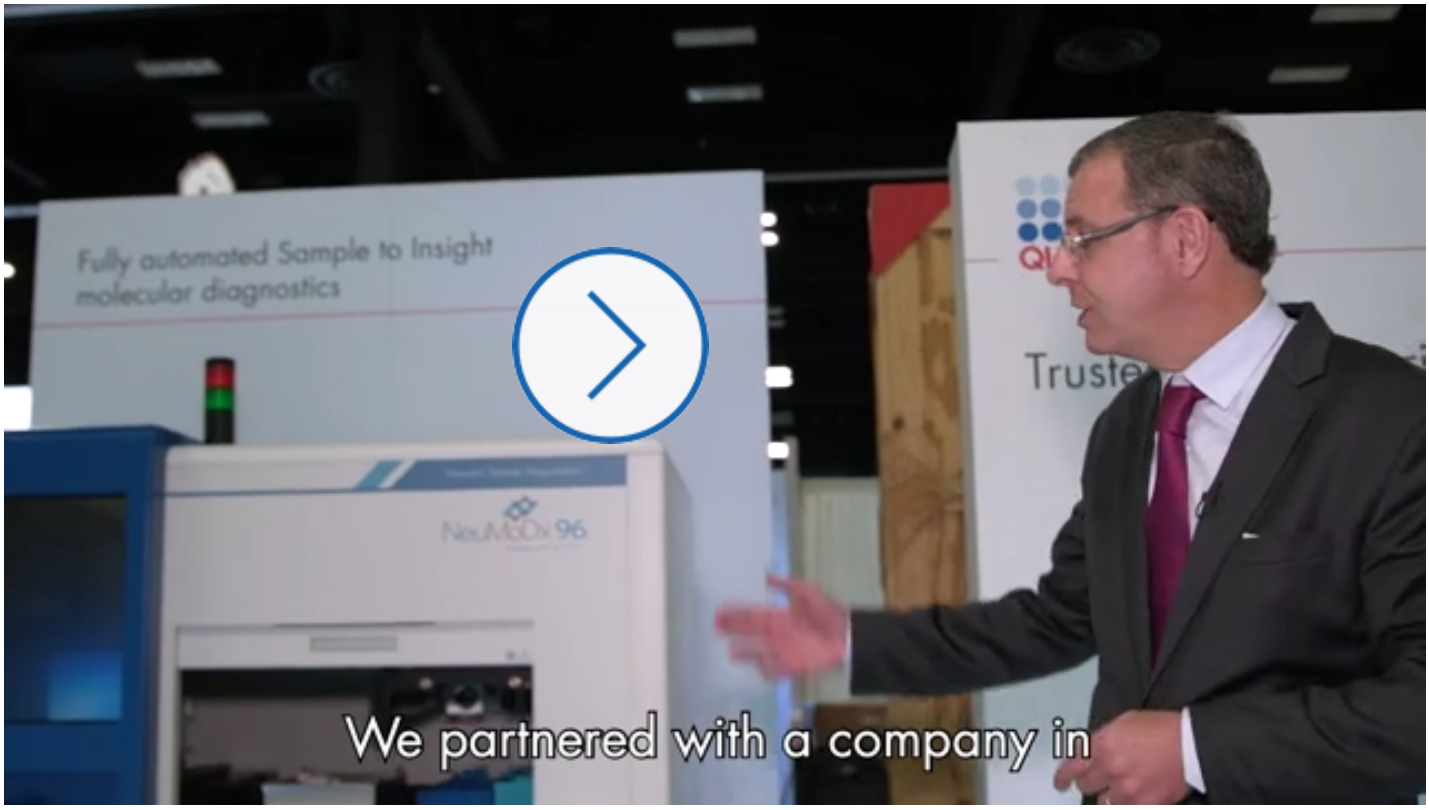
Exhibit 97

Booth Tour at AMP 2018 by Thierry Bernard



Floors open today for AMP 2019 in beautiful San Antonio, Texas. Take a tour through our booth under construction to find out what to expect from QIAGEN's presence this year. NGS, PCR, bioinformatics, syndromic testing, and a whole lot more.

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Events

(/new-insights-into-lung-cancer) **03:15**

New insights into lung cancer (/new-insights-into-lung-cancer)

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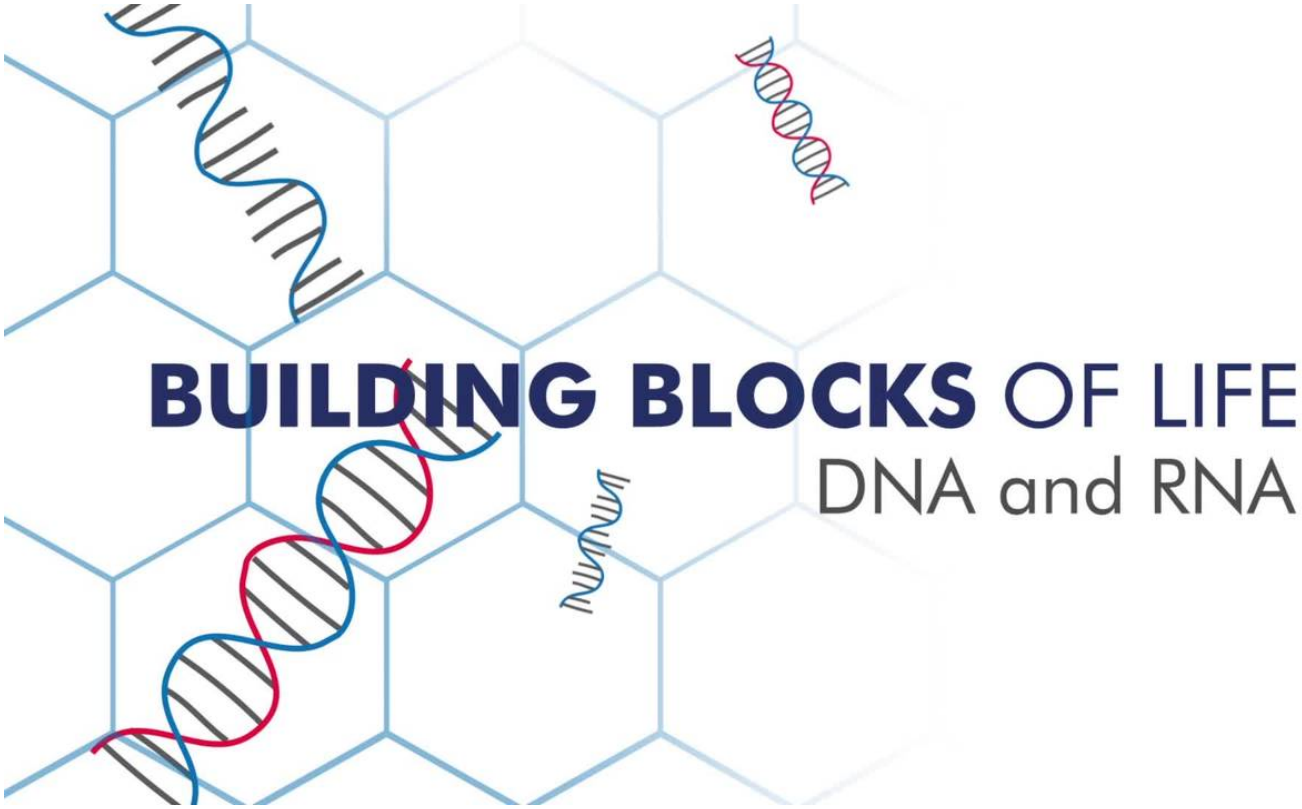
ASCO 2018 - QIAGEN CEO Peer Schatz about the development... (/asco-2018-qiagen-ceo-peer-schatz-about-the)



(/qiagen-sample-to-insight) **02:04**

QIAGEN - Sample to Insight (/qiagen-sample-to-insight)

Sample to Insight